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Instructions for Use Part #: **70-0111 / 70-0121**

Nephros HydraGuard UltraFilter

Introduction

Information on this sheet must be read before the use of this device to ensure safe and effective operation.
Recommended Storage: Between 5 and 35°C (41 and 95°F).

Indications

Description: The HydraGuard UltraFilter is a hollow fiber ultrafilter that retains bacteria, viruses, and endotoxin from water.

Indications for Use: The HydraGuard UltraFilter is intended to be used to filter EPA quality drinking water. The filter retains bacteria, viruses and endotoxin. By providing ultrapure water for patient washing and drinking, the filter aids in infection control. The filter produces water that is suitable for patient wound cleansing, cleaning of equipment used in medical procedures and washing of surgeon's hands. The filter is not intended to provide water that can be used as a substitute for USP sterile water.

Use Life: The device is intended for long term continuous use. Once it completes its useful life, the filter should be replaced and discarded. Do not attempt to sterilize or reuse it.

Contraindications

Chemical: The HydraGuard UltraFilter retains biological contaminants. To obtain chemically pure water it is necessary to use the filter in conjunction with other devices such as DI beds or RO systems.

Warnings & Precautions

Pressure & Temperature: The HydraGuard UltraFilter is intended for a maximum incoming water pressure of 100 psi (6.8 bar) and a maximum incoming temperature of 27°C (80°F).[1]

Cyclic Use: The HydraGuard UltraFilter is designed to achieve a maximum of 3,000 on/off cycles.

Replacement: The filter should be replaced when the flow rate begins to noticeably decrease. It is recommended to establish a maintenance schedule of replacing the filter at least every 6 months dependent on water quality.

Water Monitoring: After installation of the HydraGuard UltraFilter, periodic monitoring of the water is recommended. Water quality is dictated by the intended use and should be established and monitored by the facilities engineer. Nephros is available to assist with establishing guidelines and acceptance criteria as needed.

Filter Installation & Removal

New Install: If this is the first time any reusable cartridge type filter is being installed in a location (i.e. there are no cartridge housings in place), please refer to the second page of these instructions for installation guidance before proceeding with the instructions below.

Note: Prior to handling a new filter wash hands and wear disposable gloves.

- Turn off the water source upstream of the filter and vent any excess pressure from the housing via its bleed valve or outlet test valve.
- Remove both the housing bowl/cover and the old filter.
- Open a new HydraGuard UltraFilter blister pack and aseptically remove the filter.
- Insert the O-ring end of the filter into the head of the housing. It may be necessary to use a twisting motion to ensure that the filter is firmly in place and the O-rings seat properly. Re-attach the housing bowl/cover.
- Open the upstream water source and prime the new filter by opening the outlet test valve for a few minutes to purge it of trapped air (if the housing has a bleed valve, open it at the same time to assist purging).
- Close the outlet test valve (and bleed valves if present) and verify there are no leaks.

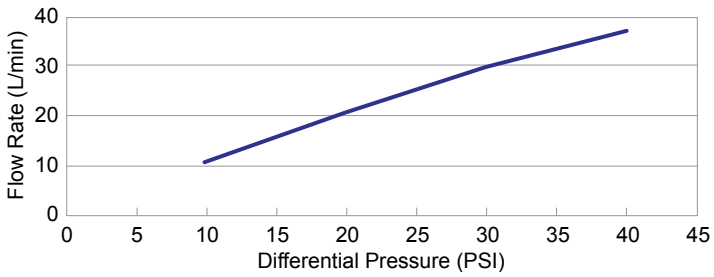
Operation

After a new HydraGuard UltraFilter is installed, water should be run through the filter for approximately 5 minutes to purge it of trapped air and any manufacturing particulates. The pressure drop across the HydraGuard UltraFilter generally reduces the flow rate by about 10-20% of the rate without a filter. The filter should operate for up to 6 months of normal use with minimal degradation in flow. If the flow rate degrades significantly, the filter should be replaced.

Integrity Testing

- The filter integrity can be verified with a pressure holding test after the filter has been properly primed and there are no connection leaks.
- Turn off the water source and open the inlet test valve to bleed off any residual pressure.
- Connect an air source (compressed air or air pump) to the inlet test port as shown in Housing and Filter Installation Example. Note that a pressure gauge must be installed to monitor the inlet filter pressure in order to carry out this test.
- Open both test valves, and pressurize the filter inlet; ensure the outlet test port is venting. Raise the air pressure to 15 psi at the filter inlet and allow water to exit from the outlet test port. Do not exceed 30 psi to prevent damage to the filter membrane.
- When water stops coming out from the outlet test port close the outlet test valve and check for external leaks (via pressure gauge).
- Open the outlet test valve and re-pressurize as necessary to reach 15 psi at the filter inlet.
- With the outlet test valve open, close the inlet test valve and allow the pressure to stabilize for 5 to 10 seconds.
- Monitor the pressure gauge and determine the pressure drop for a period of 1 minute.
- If the pressure drops by more than 1 psi over a minute, check for leaks and repeat the test to confirm. If the filter fails, it must be replaced.
- Close the outlet test valve and remove air source. Open water source valve and re-prime filter to return to operation.

Clean Water Flow Rate per 10" Segment

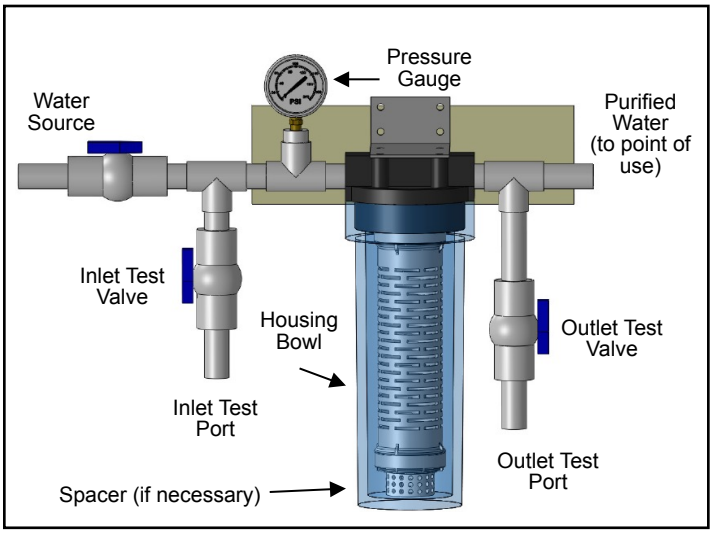


(1) For inlet pressures above 75psi, a pressure regulator should be installed (≤75psi) to account for plumbing system pressure fluctuations (typically up to +/- 25psi). A hammer arrester should be installed in applications where water hammer may be present.

Nephros HydraGuard UltraFilter (continued)

Specifications	
Max Inlet Pressure	100 psi (6.8 bar)
Max Inlet Temperature	27°C (80°F)
Max # On/Off Cycles	3,000
Material	Polysulfone
MW cut-off	15 kDa
Bacterial Retention	> 10^{11} (B. diminuta)
Virus Retention	> 10^{8} (PhiX-174)
Endotoxin Retention	> 10^{5} EU/ml
Expected Life	Up to 6 months

Housing and Filter Installation Example



Housing Installation

If no cartridge filter housing is currently installed, the initial installation of the HydraGuard UltraFilter requires tapping into an existing section of the distribution line between the water source and the equipment.

Note: HydraGuard UltraFilters are only to be installed in reusable cartridge filter housings that are rated to at least 100 psi working pressure and comply with NSF/ANSI Standard 42/61 for material (or made from pure polypropylene with no fillers, colorants, plasticizers or lubricants) and accept 222 O-ring head cartridge filters.

In general these housings have ¾" FNPT inlet and outlet connections.

A typical installation of a HydraGuard 10" UltraFilter with cartridge housing is shown in the Housing and Filter Installation Example above.

Note: Ensure that the top cap of the housing is oriented such that the inlet flow is delivered to the center (ring section) of the cap and the outlet flow comes from the bowl space (off the shelf housings may have reverse inlet/outlet labeling on housing cap). A spacer may be required for longer housings to properly seat the O-rings (contact Nephros for acceptable spacers).

Housing & Plumbing Installation

In cases where a HydraGuard UltraFilter housing is being installed for the first time or the filter is being replaced, it is recommended to disinfect the cartridge housing and downstream plumbing (faucet, equipment, etc.). This applies whether it is a new housing recently installed or an existing housing that may have contained another cartridge type filter.

Note: Disinfection should be performed with a diluted 1:100 bleach/water solution. Use personal protective equipment (gloves, lab coat, glasses, etc.) when handling the disinfectant, filter and housing to decrease any chances of contaminating the water system.

Note: Prior to handling a new filter wash hands and wear disposable gloves.

- Turn off the water source upstream of the housing and vent any excess pressure from the housing via its bleed valve (if present) or outlet test valve.
- Remove the housing bowl and used filter cartridge and empty water.
- Aseptically remove a new filter from its packaging and install the O-ring end into the top cap of the filter housing.
- Fill the housing bowl with 0.5L of a fresh bleach solution for 10" UltraFilter and 1.0L for 20" UltraFilter prepared as a 1:100 dilution of standard bleach (8.25%) per the manufacturer's instructions.
- Carefully re-assemble the housing bowl containing the bleach solution to the top cap and tighten. Be careful to avoid spillage of the bleach solution.
- Open the upstream water source.
- Slowly open the downstream valve on the equipment or faucet to purge air out of the housing and until disinfectant is observed to be flowing through the system using a chlorine test trip. Close the downstream valve.
- Slowly open the outlet test port valve and confirm the presence of bleach with a chlorine test strip. Close the outlet test valve.
- Allow the disinfectant to dwell for a minimum of 10 minutes, but no more than 30 minutes. Any longer could damage internal components of the equipment or faucet.
- Open the downstream valve and allow water to flush the disinfectant out of the filter housing and the downstream plumbing. To effectively rinse bleach from the filter housing, the flow rate should be at least 10 L/min (2.6 GPM) for 5 minutes.
- Open the outlet test valve for approximately 30 seconds to flush disinfectant from the outlet test port.
- Test the downstream water to ensure low residual disinfectant levels relative to the inlet water chlorine levels.

Note: To determine that the chlorine residuals have been effectively removed from the rinse water, Nephros recommends using Serim® Guardian Residual Chlorine Test Strips, 5100A. Follow all instructions from the manufacturer to obtain proper results.

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Symbol	Symbol Title	Standard Reference	Standard Title	Explanatory Text
	**Manufacturer**	ISO 15223-1:2021, Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the medical device manufacturer
		ISO 7000:2019, 3082	Graphical symbols for use on equipment	
	**Use by Date**	ISO 15223-1:2021, Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the date after which the medical device is not to be used.
		ISO 7000:2019, 2607	Graphical symbols for use on equipment	
	**Batch Code**	ISO 15223-1:2021, Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's batch code so that the batch or lot can be identified.
		ISO 7000:2019, 2492	Graphical symbols for use on equipment	
	**Part Number**	ISO 15223-1:2021, Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the manufacturer's part number, so that the medical device can be identified.
	**Sterilization by Ethylene Oxide**	ISO 15223-1:2021, Clause 5.2.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that has been sterilized using Ethylene Oxide.
		ISO 7000:2019, 2501	Graphical symbols for use on equipment	
	**DO NOT Resterilize**	ISO 15223-1:2021, Clause 5.2.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that is not to be resterilized.
		ISO 7000:2019, 2608	Graphical symbols for use on equipment	
	**DO NOT Use if Package Is Damaged and Consult Instructions for Use**	ISO 15223-1:2021, Clause 5.2.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates a medical device that should not be used if the package has been damaged or open.
		ISO 7000:2019, 2606	Graphical symbols for use on equipment	
	**Consult Instructions for Use**	ISO 15223-1, Clause 5.4.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the need for the user to consult the instructions for use.
		ISO 7000:2019, 1641	Graphical symbols for use on equipment	
	**Medical Device**	ISO 15223-1:2021, Clause 5.7.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the item is a medical device.
	**Unique Device Identifier**	ISO 15223-1:2021, Clause 5.7.10	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the medical device contains a Unique Device Identifier.
	**Fragile, Handle with Care**	ISO 15223-1:2021, Clause 5.3.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be handled with care.
		ISO 7000:2019, 0621	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.3	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**Rain**	ISO 15223-1:2021, Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall be kept away from rain and be kept in dry conditions.
		ISO 7000:2019, 0626	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**Keep Away from Sunlight**	ISO 15223-1:2021, Clause 5.3.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates that the device shall not be exposed to sunlight.
		ISO 7000:2019, 0624	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**Temperature**	ISO 15223-1:2021, Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Indicates the temperature limits in which the medical device can be safely exposed.
		ISO 7000:2019, 0632	Graphical symbols for use on equipment	
		ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	
	**This Way Up**	ISO 780:2015, Clause 4.4	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the correct upright position of the distribution packages for transport and/or storage.
		ISO 7000:2019, 0623	Graphical symbols for use on equipment	
	**Stacking Load**	ISO 780:2015, Clause 4.5	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages	Indicates the maximum stacking load which may be stacked on the distribution packages.
		ISO 7000:2019, 0630	Graphical symbols for use on equipment	

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