FiberFlo®
Hollow Fiber Cartridge Filters

Validation Guide: HF-200
0.2 µm

For use in Pharmaceutical, Medical,
Electronic and Dialysis applications.

MINNTECH®
FILTRATION TECHNOLOGIES GROUP

CONTENTS

PRODUCT SUMMARY

TEST SUMMARY

TEST METHODS

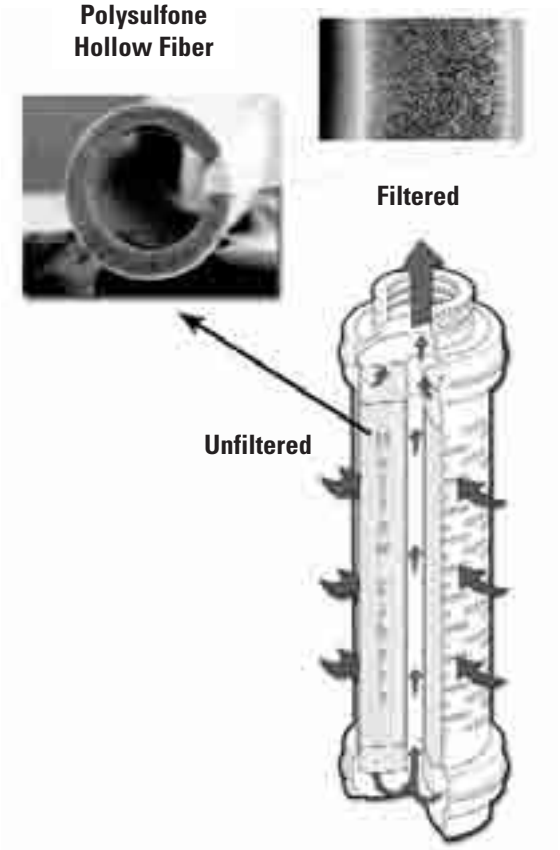
PRODUCT SUMMARY

INTRODUCTION

This validation guide has been prepared to help you assess the filtration characteristics of the FiberFlo® Hollow Fiber Cartridge Filters and relate those characteristics to your individual filtration needs. Fibercor's technical group is prepared to assist you with any specific needs not covered in this Validation Guide.

The FiberFlo Hollow Fiber Cartridge Filters have been engineered to meet the filtration needs for precise particle and bacterial removal from high purity fluids. The cartridge is manufactured by the Filtration Technologies Group of Minntech which as a manufacturer, meets or exceeds FDA Device Good Manufacturing Practice standards. In addition the manufacturing facility is ISO-9001 registered. The FiberFlo HF-200 cartridge filter has been cleared for marketing as a medical device by the FDA.

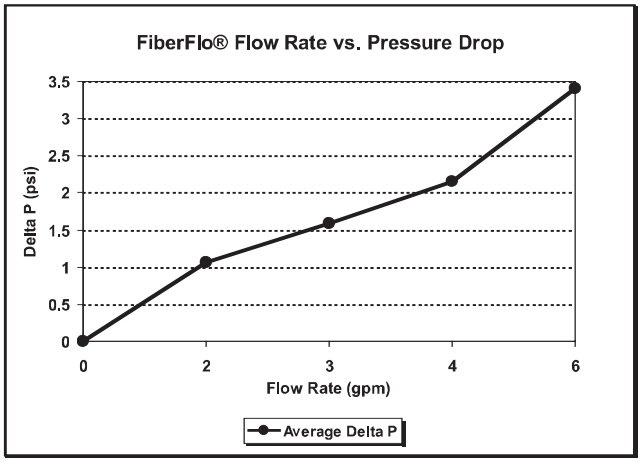
The Polyphen® polysulfone used in the FiberFlo HF cartridge filter devices is manufactured by Filtration Technologies Group under U.S. patent number 5,762,798. The asymmetric hollow fiber provides for absolute micron removal ratings, large surface area, superior flow rates and a wide range of chemical compatibility.



The FiberFlo HF Cartridge line has been tested to produce a sterile effluent when challenged with bacteria according to Health Industry Manufacturer's Association (HIMA) standards.

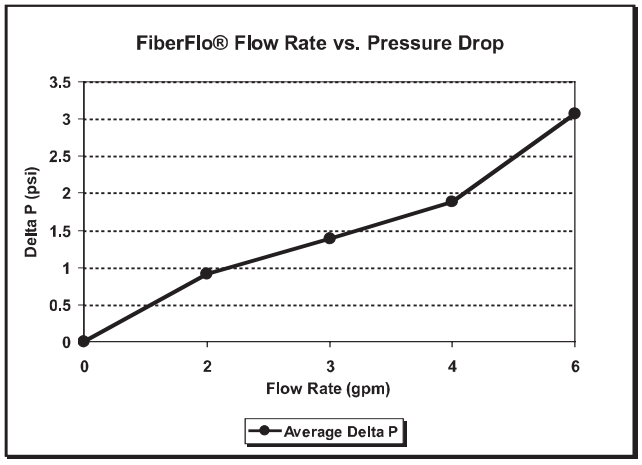
FiberFlo 200 Flow Rates at 25° ±1° C

Flow Rate	0	2	3	4	6
Average Delta P	0	1.06	1.59	2.16	3.4
Standard Deviation	0	0.107	0.16	0.234	0.347



FiberFlo 200 Flow Rates at 32° ±1° C

Flow Rate	0	2	3	4	6
Average Delta P	0	0.92	1.39	1.88	3.07
Standard Deviation	0	0.111	0.129	0.193	0.359



CATALOG NUMBERS

Catalog Number	Size	End Cap Configuration
200-103	10 inch (25.4 cm)	222 O-Ring
200-104	10 inch (25.4 cm)	222 O-Ring w/ fin
200-105	10 inch (25.4 cm)	226 O-Ring w/ fin
200-107	10 inch (25.4 cm)	119 O-Ring Internal O-Ring
200-203	20 inch (50.8 cm)	222 O-Ring
200-204	20 inch (50.8 cm)	222 O-Ring w/ fin
200-205	20 inch (50.8 cm)	226 O-Ring w/ fin
200-208	20 inch (50.8 cm)	119 O-Ring Internal O-Ring
200-303	30 inch (76.2 cm)	222 O-Ring
200-304	30 inch (76.2 cm)	222 O-Ring w/ fin
200-305	30 inch (76.2 cm)	226 O-Ring w/ fin
200-403	40 inch (101.6 cm)	222 O-Ring
200-404	40 inch (101.6 cm)	222 O-Ring w/ fin
200-405	40 inch (101.6 cm)	226 O-Ring w/ fin

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 1995

Mr. LeRoy J. Fischbach
Vice President, Regulatory Affairs
FiberCor®, Division of Minntech Corp.
14605 28th Avenue North
Minneapolis, Minnesota 55447

Re: K954349
FiberFlo™ Hollow Fiber Cartridge
Water Filters
Dated: September 15, 1995
Received: September 18, 1995
Regulatory class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Fischbach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug and Cosmetic Act (Act). You may therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you may have under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose, and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

FiberFlo®

Hollow Fiber Cartridge Filter

Housing Installation

Housings for the FiberFlo® HF should be installed as shown in Diagrams 1 or 2, with the appropriate isolation valves and pressure gauges. Diagram 1 is an example of a single filter element housing. If the filter and housing assembly are to be integrity tested, each housing should have the additional valves and fittings as shown in Diagram 3.

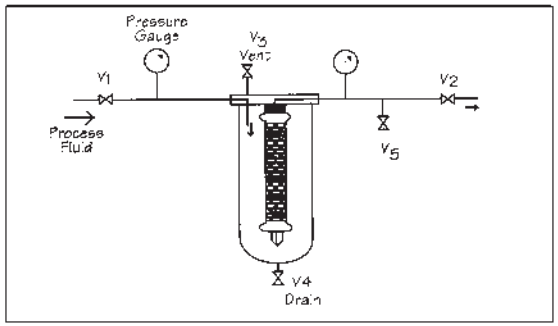


Diagram 1 - Single Housing Filter

Filter Cartridge Installation

1. Shut off flow by closing valves V_1 and V_2. To release pressure open valves V_3 and V_5. Do not attempt to remove the housing bowl/cover until pressure gauges read "0" psi.
2. Remove the housing bowl/cover and remove the old filter.
3. Open the new filter's plastic bag at the O-ring end of the cartridge (Note: Do not touch the filter directly as this will cause contamination). Wet the O-rings with distilled water or the solution being filtered. With the new filter still in the bag, push the cartridge up into the head of the housing. Use a twisting motion until the filter cartridge is firmly in place to ensure proper seating of the filter O-rings.
4. Remove the plastic bag from the filter and replace the housing bowl/cover. Partially open Valve V_3 and V_1 to fill the housing while bleeding off the air through valve V_3. When a steady stream of water is exiting valve V_3, close valve V_1, then close V_3.
5. To purge downstream air from the system, partially open valve V_5, then slowly open valve V_1 until the inlet pressure gauge reads between 45-50 psi. Throttle valves V_1 and V_5 until the inlet gauge reads between 45-50 psi (Caution: The difference between the inlet pressure and the outlet pressure should not exceed 30 psi) and there is approximately 500 ml/min flow out of the valve V_5 per 10" equivalent.
6. Allow the system to run under these conditions for 10 minutes. This will fully wet out the filter as well as provide a brief rinse of the filter.
7. Close valve V_1, then close valve V_5.
8. The filter is now ready for integrity testing or to be placed in service.

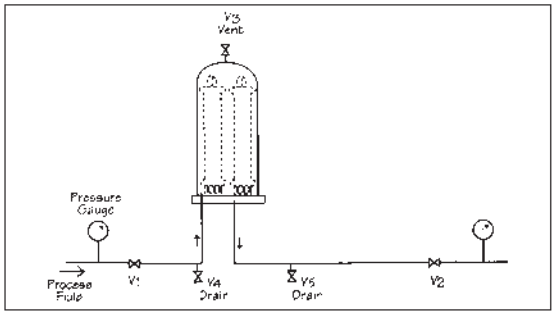


Diagram 2 - Multiple Filter Housing

Integrity Testing by Diffusive Flow

(Diagram 3)

CAUTION: DO NOT BUBBLE POINT THE FIBERFLOW® HF. BUBBLE POINT PRESSURES WILL DAMAGE THE MEMBRANE FIBERS. A DIFFUSIVE FLOW MEASUREMENT IS RECOMMENDED TO VERIFY FILTER INTEGRITY.

CAUTION: ALWAYS WEAR PROTECTIVE EYEWEAR NEAR PRESSURIZED VESSELS.

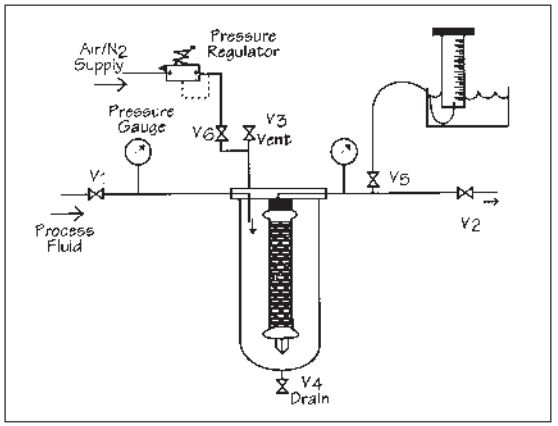


Diagram 3 - Diffusive Flow Integrity Test

1. Install and wet filters per instructions.
2. Close all valves and drain housing by opening valves V_3 and V_4. Draining the housing reduces the time required for the diffusive air flow to come to equilibrium conditions. When drained, close valves V_3 and V_4.
3. Attach flexible tubing to valve V_5. Slowly open valve V_5 and V_6, then slowly regulate the air pressure to 30 psig. Wait until a steady stream of bubbles is coming through the flexible tubing before proceeding.
4. Fill a 100 ml graduated cylinder with water and invert it in a filled collection container. Place the tubing into the submerged opening of the graduated cylinder. Measure the amount of water displaced by the air in one minute.
5. Close Valve V_5 and V_6, then slowly open V_3 to vent the pressurized air.
6. Multiply the number of ten inch equivalent filters in the housing by 80 ml/min to obtain the maximum diffusive flow for the housing.

Example: A housing containing a single 30" long filter should have a diffusive flow of less than 240 ml/min (i.e. 80 x 3 = 240).

Diffusive flow in excess of 80 ml/10" equivalent indicates that either the filters are not fully wetted or that a mechanical leak exists in the filters/housing system. If the system fails the integrity test, wet the filters again and retest.

Filter Sanitization

The following chemicals are approved as compatible with the FiberFlo HF and can be used for sanitizing. Any other chemical may damage the filter and/or O-rings and affect the filter performance.

Approved Sanitizer's and Contact:

Minncare®	1% for 30 minutes minimum 96 hrs maximum
Hydrogen Peroxide	1% for 6 hours
Sodium Hypochlorite	200 ppm 6 hours
Formaldehyde	2% for 6 hours

Sanitizing Recommendations

These guidelines are provided to support the chosen sanitizer's specific directions for use. Reference each sanitizer's material data sheet for special handling procedures.

1. Make sure the system is free from other chemicals that may react with the solution being used.
2. Mix the appropriate concentration of chemical in purified water from a reverse osmosis or deionization system. Then verify the concentration with appropriate test strips.
3. The diluted solution should be pumped through the filter housing. Alternately, the filter may be removed from the housing and soaked in the solution. If the filters are removed from the system and soaked, it is important that the entire filter be submerged and the contact time doubled. The O-rings should be removed, cleaned and then soaked separately. (Sterile gloves should be worn when handling the filter.) If the filter is disinfected more than once per month, the O-rings should be replaced every three months, only if the filter is removed from the housing.
4. After the desired contact time, the filter should be thoroughly rinsed to drain. The time required to rinse the filter will vary from system to system. Residual test strips or some other appropriate means of testing the residual concentration should be used to verify when the filter has adequately rinsed prior to placing in service.

Note: Minncare® is the recommended sanitizer because of its biocidal activity, ease of disposal, and the ability to measure residual concentrations with test strips.

Water Treatment Applications

The particular placement of FiberFlo HF filter housings in water treatment systems depends on the desired performance. One suggested location would be directly downstream of the water treatment equipment as final filtration. The FiberFlo HF will remove pyrogens, bacteria, and fine particulates that might be shed by reverse osmosis and ion exchange systems, storage tanks, filters, or by other equipment located upstream.

The FiberFlo HF also can be installed at the point of use, where the filter will remove contaminants from the water treatment equipment and from the distribution piping.

MINNTECH®
FIBERCOR DIVISION

Minntech Corporation
14605 28th Avenue North
Minneapolis, MN 55447 U.S.A.
Phone: (763) 553-3300
(800) 328-3340
Fax (763) 553-3387

Minntech B.V.
Sourethweg 11
6422PC Heerlen
The Netherlands
Phone: (31) 45 5471471
Fax (31) 45 5420695

Minntech Japan Corporation
4F Sumitomo Seimei Yochomachi Bldg.
10-10 Yochomachi, Shinjuku-ku
Tokyo 162-0555 Japan
Phone: (81) 03 (3225) 8680
Fax (81) 03 (3225) 8681

Medical Applications

The FiberFlo Hollow Fiber Filter is designed to remove particulate, remove bacteria and reduce pyrogen levels in your water system.

CAUTION: When used as a medical device, federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

CAUTION: THIS DEVICE DOES NOT TREAT WATER; IT WILL ONLY REMOVE CONTAMINANTS BY FILTRATION. TO OBTAIN CHEMICALLY PURE WATER, IT IS NECESSARY TO USE THIS FILTER IN CONJUNCTION WITH OTHER WATER TREATMENT DEVICES SUCH AS REVERSE OSMOSIS SYSTEMS OR DEIONIZATION BEDS. THIS FILTER SHOULD NORMALLY BE PLACED FOLLOWING THESE OTHER TREATMENT DEVICES.

CAUTION: THIS FILTER SHOULD BE SANITIZED WITH THE REST OF THE WATER SYSTEM OR WHEN BACTERIAL COUNTS EXCEED THE USERS ESTABLISHED LEVELS. UNDER NORMAL USAGE, IT IS RECOMMENDED THAT THE SYSTEM BE SANITIZED AT LEAST WEEKLY UNTIL THE APPROPRIATE SANITIZATION PATTERN CAN BE ESTABLISHED.

CAUTION: THIS FILTER SHOULD BE REMOVED FROM SERVICE IF THE PRESSURE DROP ACROSS IT IS 30 PSI OR GREATER. UNDER NORMAL CONDITIONS, THE FILTER IS EXPECTED TO LAST UP TO 6 MONTHS WHEN USED IN CONJUNCTION WITH A REVERSE OSMOSIS SYSTEM AND APPROXIMATELY 3 TO 6 MONTHS WHEN USED WITH A DEIONIZING WATER SYSTEM.

This filter should be integrity tested following sanitization/rinse or steam sterilization.

Other Applications

For assistance on other applications, contact Fibercor's Technical Service Department.

67733-020/F

PRODUCT SPECIFICATIONS

MATERIALS OF CONSTRUCTION

Materials of Construction

Hollow Fiber Membrane	Polyphen® Polysulfone
Casing	Polypropylene
End Caps	Polypropylene
Inner Support Core	Polypropylene
End Seals	Polyurethane
Standard O-rings	Silicone (others available upon request)
Sealing Method	Welding

Effective Filtration Area

1.5 m^2 (16ft^2) per 10 in. cartridge.
3.0 m^2 (32ft^2) per 20 in. cartridge.
4.5 m^2 (48ft^2) per 30 in. cartridge.
6.0 m^2 (64ft^2) per 40 in, cartridge.

Maximum Differential Pressure

30 PSI (2 Bar)

Integrity Test

Each cartridge is 100% integrity tested. Each cartridge may be integrity tested by the quantitative diffusive flow method. See the section entitled "Test Methods" for further information.

Cartridge Length	@ 30 psi
10 inch	≤80 ml/min
20 inch	≤160 ml/min
30 inch	≤240 ml/min
40 inch	≤320 ml/min

SUMMARY OF RESULTS

BACTERIAL CHALLENGE TESTING

Bacterial Challenge Testing

FiberFlo HF cartridge filters meet all absolute bacterial rated tests at 0.05 pore size as outlined by the Health Industry Manufacturers Association (HIMA) standard method for "Microbiological Evaluation of Filters for Sterilizing Liquids." HIMA document #3, Vol. 4, 1982.

Extractables/Solids

Passes USP standards for oxidizable substances and total solids for purified water.

Toxicity

Passes all current USP Class VI Plastics and Mouse Safety Tests

Sterilization

FiberFlo HF cartridges may be autoclaved dry or wet (121°C, 30 min.) up to 6 cycles, or steam sterilized (190°F, 100 min.) up to 30 cycles.

Certification

All Filtration Technologies Group hydrophilic 0.2 µm cartridges have a Certificate of Analysis available upon request, which assures that each cartridge is manufactured and tested to the specifications designated in this guide. This certificate provides the part number, lot number, performance testing (water flux, diffusive flow, and endotoxin removal), latex bead challenge, biocompatibility and solids/extractables.

FiberCor®

Division of MINNTECH® Corporation

certifies that

Description: FiberFlo 200

Part Number: XXXXX-XXX

Lot Number: XXXXX

has been manufactured in a controlled environment in accordance with the requirements of the Current Good Manufacturing Practices (21 CFR Part 820) as published in the Federal Register of the United States of America.

*MINNTECH® Corporation is an ISO 9001 certified company.

[X] **PERFORMANCE**

This lot successfully passed performance testing for Water Flux, Diffusive Flow, and Endotoxin Removal.

	*SPECIFICATIONS	*Actual
Water Flux	ΔP @ 3.0gpm ≤ 5.0 lbs/sq. in.	pass
Diffusive Air Flow	≤ 80 ml/min	pass
Endotoxin Removal	≤0.06 Eu/ml	pass

*Specifications and Actuals are based on 10" units.

[X] **BEAD CHALLENGE**

Unit fiber lot conformed to established bead challenge criteria.

[X] **SOLIDS / EXTRACTABLES**

Passes USP standards for oxidizable substances and total solids for purified water.

[X] **DIMENSIONS**

All fiber included herein conform to established dimensional criteria.

[X] **BIOCOMPATIBILITY**

All fiber components are made from materials tested for safety according to the Class VI methods of the latest revision of the ***United States Pharmacopeia.***

MINNTECH Corporation
14605 28th Avenue North
Plymouth, Minnesota 55447
Telephone: (612) 553-3300
Fax (612) 553-3387

_____

Quality Assurance Department

Chemical Compatibility

KEY

1	=	Fully Compatible
2	=	Limited Compatibility
3	=	Not Recommended
-	=	Insufficient Data

Ratings are defined as follows:

Acids	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Acetic Acid, glacial	3	2
Acetic Acid, 90%	-	2
Acetic Acid, 30%	-	1
Acetic Acid, 10%	-	2
Chromic Acid, conc.	-	3
Hydrochloric Acid, conc.	1	3
Hydrochloric Acid, 6N	-	3
Hydrofluoric Acid, 6N	-	3
Nitric Acid, conc.	3	2
Nitric Acid, 6N	-	2
Phosphoric Acid, conc.	-	3
Sulfuric Acid, conc.	3	3
Sulfuric Acid, 6N	-	3
Minncare, 1%	1	1
Renalin, 1%	1	1

Alcohols	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Amyl Alcohol	1	3
Benzyl Alcohol, 100%	1	2
Benzyl Alcohol, 3%	3	1
Butanol	1	3
Ethanol	1	1
Isopropanol	1	1
Methanol	1	1
Propanol	1	1

Bases	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Ammonium Hydroxide, 3N	1	1
Ammonium Hydroxide, 6N	1	1
Potassium Hydroxide, 3N	1	2
Sodium Hydroxide, 3N	1	1
Sodium Hydroxide, 6N	1	1

Esters 100%	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Amyl Acetate	-	1
Butyl Acetate	-	1
Cellosolve Acetate	1	1
Ethyl Acetate	2	1
Isopropyl Acetate	1	2
Methyl Acetate	3	-

Ethers FiberFlo	Silicone HF 200 Filter	Rubber O-Ring
Ethyl Ether	1	3
Isopropyl Ether	-	3
Dioxane	-	3
Tetrahydrofuran	3	3

Glycols	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Ethylene Glycol	1	1
Glycerol	1	1
Propylene Glycol	3	1

Aromatic Hydrocarbons	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Benzene	2	3
Toluene	2	3
Xylene	2	3

Halogenated Hydrocarbons	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Carbon Tetrachloride	2	3
Chloroform	3	3
Chlorothene® NU	-	3
Ethylene Dichloride	3	3
Freon® TF	1	3
Freon-M TMC	3	3
Genosolv® D	1	3
Methylene Chloride	3	3
Perchloroethylene	2	3
Trichloroethylene	2	3

Ketones	FIberFlo HF 200 Filter	Silicone Rubber O-Ring
Acetone	3	3
Cyclohexanone	3	3
Methyl Ethyl Ketone	-	3
Methyl Isobutyl Ketone	3	3

Oils	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Cottonseed Oil	-	1
Lubrication Oil MIL-L-7808	3	1
Peanut Oil	-	1
Sesame Oil	3	1

Photoresists	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Positive	3	3
Negative	-	3

Miscellaneous Photoresists	FiberFlo HF 200 Filter	Silicone Rubber O-Ring
Acetonitrile	1	-
Aniline	3	3
Dimethyl Formamide	3	1
Dimethyl Sulfoxide	3	3
Formaldehyde, 37%	1	1
Formaldehyde, 4%	1	1
Gasoline	1	3
Hexane, dry	2	3
JP-4	1	3
Kerosene	1	3
Nickel Sulfate Solution	-	1
Phenol, liquefied	3	3
Pyridine	3	3
Skydol® 500	1	2
Turpentine	1	3
High Purity Water	1	1

TEST SUMMARY

BIOLOGICAL TESTING

Bacterial Retention

In order to show that FiberFlo water filters remove bacteria from the input water, testing was conducted by an outside lab. The challenge suspension contained approximately 10^7 Brevundimonas diminuta ATCC 19146* bacteria/cm^2 filtered through a FiberFlo water filter with a 0.2 µm pore size. B. diminuta was selected because of its small size. The filtrate from the water filter was collected in a sterile container and then assayed. The results showed 0 (none) CFU of bacteria in the filtrate. This demonstrated that the FiberFlo cartridge water filter blocked all of the bacteria.

Filter Number	Challenge	Flow Rate Pressure	Total Challenge	Challenge / sq. ran	Filtrate Count	Rinse Count	Log Reduction
FF 200 Cartridge 20 sq. cm., 0.2 µm Lot 6323-02-19 #1	30 PSIG	220 mL/57 sec.	2.40E+09	1.2E+08	None detected	None detected	> 9.4
FF 200 Cartridge 20 sq. cm., 0.2 µm Lot 6323-02-19 #2	30 PSIG	220 mL/59 sec.	2.40E+09	1.2E+08	None detected	None detected	> 9.4
FF 200 Cartridge 20 sq. cm., 0.2 µm Lot 6330-02-07 #1	30 PSIG	220 mL/76 sec.	2.40E+09	1.2E+08	None detected	None detected	> 9.4
FF 200 Cartridge 20 sq. cm., 0.2 µm Lot 6330-02-07 #2	30 PSIG	220 mL/75 sec.	2.40E+09	1.2E+08	None detected	None detected	> 9.4
FF 200 Cartridge 20 sq. cm., 0.2 µm Lot 6330-02-07 #3	30 PSIG	220 mL/81 sec.	2.40E+09	1.2E+08	None detected	None detected	> 9.4

*Brevundimonas diminuta ATCC 19146 is now preferred over Pseudomonas diminuta in the filtration industry.

Toxicity

USP Class VI Plastic and Mouse Safety Tests were used to confirm the suitability of FiberFlo HF cartridge construction materials and assembled cartridges for contact with parenterals.

VIROMED LABORATORIES, INC.

USP Class VI Certificate

Sponsor: Minntech/Fibercor
14605 28th Ave., N.
Plymouth, MN 55447

Test Article: Fiber Flo Cartridge Filter

Lot #: 6013A

The test article named above was tested using the following tests for Class VI Certification. The results of each test are listed below.

TEST	EXTRACTS	RESULTS
USP Acute Systemic Toxicity Project #3026	0.9% Normal Saline Cotton Seed Oil Ethanol in Saline Polyethylene Glycol	PASS
USP Intracutaneous Toxicity Project #3027	0.9% Normal Saline Cotton Seed Oil Ethanol in Saline Polyethylene Glycol	PASS
	DETAIL	
USP Muscle Implant Project #3028	Fiber Material	PASS
USP Muscle Implant Project #3029	Inner Plastic Tubing Surgical implant	PASS
USP Muscle Implant Project #3030	Outer Plastic Shell Surgical implant	PASS

All of the tests have passed according to the USP requirements.

The test article, Fiber Flo Cartridge Filter Model 100-203, is therefore issued this USP Class VI Certificate.

Approval: David L. Hodge Date: 12-31-96
David L. Hodge, BA, LAT
Director of In Life Studies

CHEMICAL TESTING

Gravimetric Extractables

Testing was performed to determine the amount of non-volatile extractables in a 10 inch FiberFlo filter. Refer to the section entitled "Test Methods" for a full description of the test performed.

Product	Extractables mg/cartridge
FiberFlo 200	3.6

Compatibility

The chemical compatibility is based on the materials used in construction of the cartridge filter as well as any and all components used in the test. Filtration Technologies Group has generated results based on in house testing and on data accumulated by outside sources. Temperature, viscosity and other components can affect the testing differently. Filtration Technologies Group recommends that each customer test before hand the chemical in question before use in the system.

PHYSICAL AND PERFORMANCE TESTING

Latex Bead Challenge Test

The latex bead challenge test was used to determine the absolute pore size of the FiberFlo 200 filter. Fifteen polysulfone fibers were potted in a polycarbonate module. The module was then fully wetted. A latex bead solution containing beads of the appropriate size (0.2 µm) for the filter was forced through the filter at a pressure between 300 to 400 mmHg. The outlet fluid was passed through an analytical filter disk and into a vacuum flask. Spectraphotometric analysis was performed to detect beads in either the collected effluent or on the outlet filter. Additionally, scanning electron microscopy was performed on the analytical filter disk. No beads were found on the disk using either method, nor were any found in the effluent. The protocol used for this test is included in the test protocol section.

Autoclave/Live Steam Sterilization

FiberFlo Hollow Fiber Cartridge Water Filters were tested for their ability to withstand autoclave sterilization. The procedure autoclaved filters at 121°C for 30 minutes. The filters were tested dry (out of the box) and wetted (as described in the instruction for use.) The results are summarized in the table below.

Flow Rate GPM	Specification	D P After A/C, Dry	D P After A/C, Wet
1	0.6	0.7	0.8
2	1.1	1.1	1.2
3	1.6	1.6	1.8
4	2.2	2.2	2.4
5	2.8	2.9	3.2
6	3.4	3.4	3.7
Diffusive Flow (ml/min)	Less than 80	Less than 80	Less than 80

Tests were also performed to indicate the tolerance of the

FiberFlo water filters to steam sterilization. A full description of the in-line steam test is located in the section entitled "Test Methods." The results of this testing is shown in the table below.

Flow Rate GPM	Specification	D P After A/C, Dry	D P After A/C, Wet
2	1.1	1.1	1.2
3	1.6	1.5	1.6
4	2.2	2.3	2.4
5	2.8	2.9	3.0
6	3.4	3.4	3.5
Diffusive Flow (ml/min)	Less than 80	Less than 80	Less than 80

The autoclave/steam sterilization test results demonstrate that all units met the factory specification for maximum pressure drop. Pressure drops measurements are the most often used criteria when using heated methods of sterilization. The units passed all other functional release testing as well.

Diffusion

FiberFlo Hollow Fiber Cartridge Filters are integrity tested by the quantitative diffusive flow method. Diffusive flow less than 80 ml per 10 inch equivalent indicates that all fibers are intact. A complete description of the Diffusive Flow test method is located in the section entitled "Test Methods."

Pressure Decay

Pressure decays were observed over a 1 minute time period. All values were within 2 - 15 mmHg (0.039 - 0.290 PSIG). Results are shown in the table below.

Product	P_{in} (mmHg) 0 minutes	P_{out} (mmHg) 0 minutes	ΔP (mmHg)
FiberFlo 200	423	417	6
FiberFlo 200	407	404	
FiberFlo 200	411	408	3

A complete description of the pressure decay test appears in the section entitled "Test Methods."

TEST METHODS

BIOLOGICAL TESTING

Bacterial Retention

Testing was performed at Nelson Laboratories, Inc. located in Salt Lake City, Utah. A complete protocol is available upon request.

Toxicity Testing

Testing was performed according to USP Class VI standards at ViroMED Laboratories, Inc., located in Minneapolis, Minnesota. A complete protocol is available upon request.

CHEMICAL

Gravimetric Extractables Test

Purpose

To determine the amount of non-volatile extractables in a 10" FiberFlo® 100 filter.

Materials

Aluminum Foil
Oven, 80°C ±0.5°C
Desiccator
Analytical Balance
Beakers, Acid Washed
Hot Plate
Reagent Grade Water
Glass Cylinder

Procedure

Place the cartridge in a glass cylinder. Add a known amount of pure water to the cylinder, sufficient to cover the cartridge. Cover with aluminum foil and let stand undisturbed for 24 hours. Remove Cartridge. Transfer 250 ml of the extraction water to a clean desiccated, tared beaker (±0.5mg). Boil almost to dryness. Place beaker in a 80°C oven until water is evaporated. When dry, place in a desiccator to cool. Weigh the cooled beaker and residue (±0.05mg).

Repeat the above steps starting with "transfer 250ml" using pure water. This will serve as a control.

Calculations

A. **Sample**
   Weight of beaker and residue)-(Weight of beaker) = Cartridge extractables
B. **Control**
   (Weight of beaker and residue)-(Weight of beaker) = Control extractables
C. **Result**
   [(Cartridge extractables)-Control extractables)] x [Extraction volume/250] = Extractables/cartridge.

PHYSICAL AND PERFORMANCE TESTING

Latex Bead Challenge Protocol and Sample Data

OBJECTIVE: The objective of this test procedure is to verify the pore size rating of fiber that is produced for the FiberFlo water filter at 0.2 microns.

Equipment and Supplies

QUANTITY	DESCRIPTION
300 ml	0.10 Reagent Grade Water
1.25 ml	0.09 diameter polystyrene beads
2	Luer stopcocks
1	Digidyne® pressure monitor
1	500 ml beaker
2	60 cc luer lock syringe
1	13 mm stainless filter holder
1	0.05 Nucleopore polycarbonate filter
1	Rubber stopper with hole
1	Vacuum Source
1	15 fiber test mat
2	Headers for 250 case
2	Header nuts for 250 case
2	O-rings for 250 case
1	+ inch dead end
a/r	+ inch blood tubing
a/r	+ inch vacuum tubing
1	Teflon® stir bar
5	Cuvettes
1	Spectrophotometer (Beckman)
a/r	D. I. Water
1	Stand
a/r	Disposable Pipettes
1	Petri dish
1	10 ml polypropylene cup
1	+ inch tube X luer adapter

Procedure

A. Cleaning

1. Where possible use new component / supplies that are disposable. Any components that contact the water or bead solution that are not disposable, must be thoroughly cleaned.
2. The cleaning procedure for all components other than the filter holder is through washing with detergent, followed by complete rinsing in DI water, then air dried at 70-100°F.
3. The cleaning procedure for the filter holder is to disassemble and soak submerged in Methylene Chloride for 20 minutes, followed by air or convection oven drying at 70-150°F.

B. Test Mat Preparation

1. The test mat should be fully wetted out per procedure titled "WETTING OUT OF 15 FIBER TEST MATS". (available upon request)
2. The test amt should be tested for integrity per procedure titled "LEAK TESTING OF 15 FIBER TEST MATS". (available upon request)

C. Bead Solution Preparation

The bead solution is prepared by combining 1.25 grams of Duke Scientific 0.2 mm concentrated beads to 125 ml of reagent grade water in the 500 ml beaker. The mixture is then stirred on a stir plate or other suitable means for 20 minutes. A sample of the bead solution is to be read on the spectrophotometer at 90-110 ppm.

D. Assembly

The test mat should be assembled per figure #1 with the luer stopcocks, headers, header nuts, O-Rings, one end sealed with the + "dead end," and collection syringe installed. Insure that the Digi-Dyne is connected.

E. Priming of the Test Mat

Aspirate 60 cc of the bead solution into the feed syringe, and connect the syringe to stopcock #1. Open stopcock #1. Open stopcock #2 to vent the air. Slowly inject the bead solution while purging the air from the system. Close both stopcocks. Repeat this procedure until all air is purged form the casing around the fibers. Verify that the Digi-Dyne is connected and stopcock #2 is positioned such that the Digi-Dyne will display the pressure inside the case.

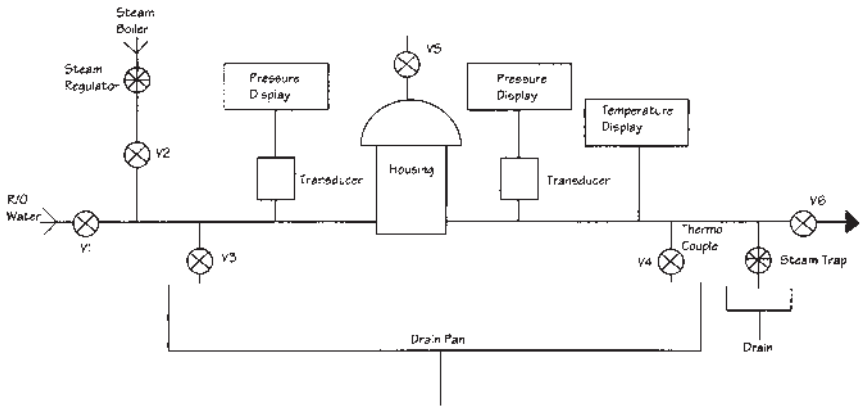
F. Conducting the Challenge

1. Aspirate 30 cc of bead solution into the syringe and connect the syringe to stopcock #1. Open the stopcock to position B.
2. Insure that the Digi-Dyne is connected and that stopcock is positioned such that the Digi-Dyne is reading the pressure inside the case.
3. Depress the piston of feed syringe to force the bead solution across the membrane in the test mat. Depress the piston at a rate such that the Digi-Dyne reads 500-550 mmHg. Continue depressing the piston until all 30 cc of bead solution have been dispensed. This will take up to 10 minutes.
4. Remove the collection syringe from the assembly and dispense approximately 2 ml of filtrate into a Cuvette for analysis. Cap the syringe with its original stopper.
5. Read the collected sample on the spectrophotometer.

In-line Steam Sterilization

Objective:

Determine the capability of FiberFlo filters to withstand in-line steam sterilization.

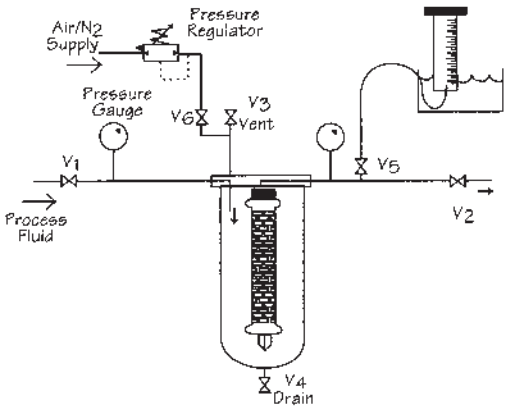


Procedure:

Assemble a test apparatus as shown in the accompanying schematic diagram. Adjust the steam pressure regulator to 20 psi.

3. With all valves in their closed position, install the filter into the housing and secure with a clamp.
4. Open Valves V3, V4 and V5 to vent the incoming steam.
5. Slowly open Valve V2 to let steam enter the system. (Note: this valve must be throttled to prevent the differential pressure from exceeding 3 psi.)
6. Drain any condensate until the system heats up. Close valves V3, V4 and V5 when a steady flow of steam is observed.
7. Slowly open Valve V2 until the downstream pressure gauge reads 20 psi. Maintain differential pressure at < 3 psi. When necessary, adjust the pressure via the steam regulator valve.
8. Maintain the system at 121° C and 20 psi for 30 minutes.
9. Close Valve V2 and cool the system to room temperature.
10. Perform flow vs. pressure drop and diffusive flow integrity tests on each filter.

Diffusive Flow Test



1. Install and wet filter as described in the Directions for Use.
2. Close all valves and drain housing by opening valves V3 and V4. Draining the housing reduces the time required for the diffusive air flow to reach equilibrium conditions. When drained, close valves V3 and V4.
3. Attach flexible tubing to valve V5. Open valve V5 and V6, then slowly regulate the air pressure to 30 psig. Wait until a steady stream of bubbles is coming through the flexible tubing before proceeding.
4. Fill a 100 ml graduated cylinder with water and invert it in a filled collection container. Place the tubing into the submerged opening of the graduated cylinder. Measure the amount of water displaced by the air in one minute.
5. Close valve V5 and V6, then slowly open V3 to vent the pressurized air.
6. Multiply the number of ten inch equivalent filters in the housing by 80 ml/min to obtain the maximum diffusive flow for the housing.
7. Example: a housing containing a single 30 inch filter should have a diffusive flow of less than 240 ml/min (i.e. 80 x 3 = 240).

   Diffusive flow in excess of 80 ml/ten inch equivalent indicates that either the filters are not fully wetted or that a mechanical leak exists in the filters/housing system. If the system fails the integrity test, wet and test the filters again.

Pressure Decay Test

1. Install the filter in the filter housing according to the Directions for Use.
2. Wet the filter using a minimum of 0.5 gpm water flowrate and back pressure the cartridge by partially closing the discharge valve to a pressure of 30 to 40 psig for at least ten minutes. Note: do not create a pressure drop greater than 30 psig from the inlet to the outlet. Pressure drops greater than 30 psig may damage the filter cartridge.
3. After the filter cartridge has been thoroughly wet, stop the water supply and drain the filter housing. Connect an air supply to the inlet of the filter cartridge and pressurize to 7.7 psig or 400mmHg using an accurate pressure monitor device.
4. Open a valve to drain from the outlet side of the filter housing. Close the air supply valve. Ensure that the pressure monitor device is between this valve and the filter housing.
5. Observe the pressure decay over a one minute period. The decay should be between 2 - 15 mmHg or 0.039 - 0.290 psig for a properly wetted, undamaged filter.

Note: The volume of the system (the filter housing and the distance of the isolation valves from the filter housing) affects the results of this test. Generally, a use history will have to be developed for the given filter/housing system being used.

MINNTECH®
FILTRATION TECHNOLOGIES GROUP

Minntech Corporation
14605 23th Avenue North
Minneapolis, MN 55447-4822
U.S.A.
Tel: (763) 553-3300
Toll Free: (800) 328-3379
Fax: (763) 553-3387

Minntech B.V.
Sourethweg 11
6422PC Heerlen
The Netherlands
Tel: (31) 45 5 471471
Fax: (31) 45 5 423695
www.minntech.com

Minntech Japan Corporation
4F Sumitomo Seimei Yochomachi Bldg.
10-10 Yochomachi, Shinjuku-ku
Tokyo 162-0055
Japan
Tel: (81) 3 (3225) 8680
Fax: (81) 3 (3225) 8681

Minntech International
Singapore Representative Office
No. 138 Robinson Road
#15-09/10 The Corporate Office
Singapore 068906
Tel: +65 6227 9698
Fax: +65 6225 6646