# PROCESS MONITORING



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Product Application Table	NovaSeptum Systems	Steritest™ Media/Device/Hardware	Milliflex® Media/Device/Hardware	Microfil® Media/Device/Hardware	55-Plus™ Monitor	
Microbiological Analysis by Membrane Filtration						
Bioburden testing			•	•	•	
Microbial limit testing			•			
Water testing			•	•	•	
Beverage samples			$\diamond$	•	•	
Sampling Solutions						
On-line sampling	•					
Sampling in aseptic & sterile processes	•					
Sterility Testing		•				
Rapid Microbiological Detection						
Bioburden & water samples			•			
Mycoplasma						
Environmental Monitoring						
Air monitoring						
Surface monitoring						
Validation and Consultancy Services						
Validation support	•	•	•			
Equipment maintenance & repair services		•	٠	•		
Method & application development		•	•			
Routine & Customized Testing						
<i>Mycoplasma</i> testing						
Nucleic Acid techniques (NAT)						
Bacteriology testing						
Virology testing						

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EZ-Pak® Device/Hardware	S-Pak® Media/Device/Hardware	M Air T® Media/Device/Hardware	MicropreSure <sup>®</sup> System	Dip & Swab Samplers	MilliPROBE® System	Milliflex Rapid System	Milliflex Quantum Media/Device Hardware System*	MTC-NI® System	MicroSafe® Biosafety Solutions Laboratory, Europe
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Product Application Table

MILLIPORE

PROCESS MONITORING

# Sterile Sampling Solutions



**PROCESS MONITORING** 

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# NovaSeptum Sterile Sampling Systems

# Sterile, Closed, Disposable Systems for Sampling Fluids From Sterile and Aseptic Processes



#### BENEFITS

- · Disposable and closed unit, ensuring the security of the process, the operator and the sample
- · Easy to use and handle, reducing operator trainer time
- · Pre-sterilized, eliminating the need for cleaning and/or sterilization between samples
- · Flexible, accommodating a wide range of sampling volumes that can connect to a variety of processes

In today's biopharmaceutical market, sampling your product is critical during every manufacturing process. An imprecise or false positive result cannot only lead to quarantine, but may also require a repeat of the analysis. With the NovaSeptum Sampling system, contamination is no longer a threat. Ideal for general fluid and cell culture sampling from aseptic and sterile processes, NovaSeptum sterile sampling units can easily protect your bioreactor from cross contamination. The closed design ensures vour sample will be isolated from point of sample to analysis, reducing the loss of valuable product.

The NovaSeptum High Purity Sampling Units ensure optimum performance, eliminating both process and sample contamination. These units are ideally suited for sterility testing, bioburden testing, endotoxin testing, chemical analysis, pH analysis, fermentation applications and applications requiring very low affinity for proteins, complex carbohydrates or small molecules.

These units are available in flat or eyeball format. The flat bag is easy to store and hang while the eyeball bag enables volume control.

The NovaSeptum General Sampling System includes a 1 mm diameter needle in the septum, which is suitable for the majority of sampling applications.

The Cell Culture Sampling System includes a 2 mm diameter needle, enabling significantly higher flow rates. which are often required in applications such as bacterial counting and sampling from bioreactors.

The NovaSeptum Sampling Units for autoclavable applications are suitable for integration into processes that are subjected to complete autoclaving cycles, such as small-scale fermentor vessels. These units are available in various sampling configurations that can be used for biological testing and chemical analysis.

Sampling high value products can be a challenge if the sample cannot be taken with an accurate volume. As a result, this uncertainty can lead to expensive product waste. Millipore understands the importance of sampling smaller volumes in order to minimize costs. Our unique syringe design in the NovaSeptum AV Sampling Units allow for small accurate samples from 1 up to 20 mL to be taken.

With the closed design of the NovaSeptum Transfer Units, you can ensure your sample will be isolated from point of sample to analysis, eliminating any risk of contamination. These units are ideal for applications such as pH regulation and fermentation inoculation.

#### MicroSafe Biosafety Solutions Laboratory, Europe

MicroSafe Biosafety Solutions Laboratory, Europe, our GMP/GLP compliant contract laboratory, offers a broad range of standard and custom mvcoplasma, virus and bacteriology testing that meets regulatory requirements. We can also assemble a team of experienced scientists to design and set up the assays you need.

For additional information, please refer to our Access Services section under Process Monitoring.

# NovaSeptum Sterile Sampling Systems

#### NOVASEPTUM LARGE VOLUME STERILE SAMPLING UNITS

	High Purity Flat Bag	High Purity Eyeball Bag	Autoclavable		
Sampling Unit Volume	50 mL to 1000 mL	100 mL	50 mL to 1000 mL		
Maximum Bag Pressure Conditions (at 25 °C)	0.50 bar up to 250 mL 0.30 bar for 1000 mL and multi-sampling	0.50 bar for single sampling 0.30 bar for multi-sampling	0.30 bar (4.35 psi)		
Temperature Range	-20 to 50 °C (-4 to 122 °F)**	0 to 50 °C (32 to 122 °F)	-20 to 125 °C (-4 to 257 °F)		
Materials of Construction			,		
Trigger					
Septum:	Medical grade platinum-cure	d silicone			
Body:	Polyester	Polyester			
Cannula:	ASTM 316L Stainless steel				
Sampling Bag:	Polyethylene film (PureFlex film)	PET (Polyethylene terephtalate)/	Polypropylene film PE (Polyethylene)		
Fluid Contact Layer:	Polyethylene film	•	Polypropylene film		
Tubing:	Polyethylene		Silicone		
Drainage Bag (valid for multi-sampling application):	Polyethylene film (PureFlex film)		Not Applicable		
Fittings					
Inlet Tubing:	Septum with a 1 mm or a 2 r	mm needle			
Outlet Tubing:	Tubing: 3-piece Luer, contair injection site	ning a male, female and an	Tubing: Male Luer with Female cap		
Autoclaving*	Not autoclavable		Autoclavable		
USP <88> Class VI	All components in contact wi	All components in contact with sampling liquid conform with USP <88> Class VI.			
Integrity Testing	Units are integrity tested at r	egular intervals during manufacturing	].		
Assembly	Assembled under ISO Clean	Room Class 8 conditions in a facility	y certified to ISO 14644-1		
Sterilization	The sampling units are steril	ized by beta irradiation at $\ge$ 25 kGy a	according to ISO 11137		
Bacterial Endotoxin	Aqueous extraction contains < 2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test				

\* Autoclaving can only be performed on empty bags. \*\* -80 to 50 °C coming soon.

**PROCESS MONITORING** 

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PROCESS MONITORING

#### NOVASEPTUM SMALL VOLUME STERILE SAMPLING UNITS AND TRANSFER SYSTEM

	Accurate Volume	Bag Transfer System	Tube Transfer System			
Sampling Unit Volume	5 mL and 20 mL	250 mL	Not applicable			
Maximum Bag Pressure Conditions (at 25 °C)	0.50 bar (7.25 psi)					
Temperature Range						
	Single 5 mL: -20 to 123 °C** (-4 to 253 °F)	-20 to 50 °C (-80 to 50 °C coming soon)	Polyethylene: -20 to 50 °C (-80 to 50 °C coming soon)			
	Single 20 mL: -20 to 121 °C**		Silicone: -50 to 95 °C			
	(-4 to 250 °F)		(-80 to 95 °C coming soon)			
	Multi: -20 to 50 C (-4 to 122 °F)					
Materials of Construction			·			
Trigger						
Septum:	Medical grade platinum-cured silic	cone				
Body:	Polyester	Polyester				
Cannula:	ASTM 316L Stainless steel	ASTM 316L Stainless steel				
Sampling Bag:	Not Applicable	PureFlex film	Not applicable			
Fluid Contact Layer:	Polycarbonate, medical grade platinum-cured silicone, medical silicone fluid	Polyethylene	Not applicable			
Tubing:	Silicone	Polyethylene	Polyethylene or Silicone			
Drainage Bag (valid for Multi-Sampling Application):	Polyethylene film (PureFlex film)	Not Applicable	Not Applicable			
Fittings						
Inlet Tubing:	Septum with a 1 mm or a 2 mm n	eedle				
Outlet Tubing:	Tubing: male and female Luer	Septum Unit with a 1 mm or 2 mm needle	3-piece Luer, containing a male, female and an injection site			
Autoclaving*	Not autoclavable***	Not autoclavable	Not Autoclavable			
USP <88> Class VI	All components in contact with sa	mpling liquid conform with USF	v <88> Class VI.			
Integrity Testing	Units are integrity tested at regula	r intervals during manufacturing	g.			
Assembly	Assembled under ISO Clean Roo	m Class 8 conditions in a facilit	y certified to ISO 14644-1			
Sterilization	The sampling units are sterilized t	oy beta irradiation at ≥ 25 kGy a	according to ISO 11137			
Bacterial Endotoxin	Aqueous extraction contains < 2.1 Amebocyte Lysate (LAL) test	Aqueous extraction contains < 2.15 EU per device as determined using the Limulus Amebocyte Lysate (LAL) test				

\* Autoclavable can only be performed on empty bags.
 \*\* -80 to 134 °C coming soon
 \*\*\* Single: autoclavable coming soon

# NovaSeptum Sterile Sampling Systems

#### SPECIFICATIONS (CONTINUED)

#### NovaSeptum Holders

Materials of Construction	
Wetted materials:	Stainless steel 316L, EN 1.4435
Magazine (blue plastic holder portion):	Polyphenylene sulfide (PPS)
Autoclavable/Steam-in-Place	Yes
Tube Standards	
TC and Ingold <sup>®</sup> :	N/A
In-line TC, In-line Butt-end:	ASTM <sup>®</sup> A270, DIN 11850 (Part 2)
NovAseptic Connectors	
Materials of Construction	
Wetted materials:	Stainless steel 316L, EN 1.4435
Tube Standards:	ASTM A270, DIN 11850 (Part 2)
Connection Type:	Butt-end or TC

For additional information on configured products, please contact your local Technical Service Representative.

#### ORDERING INFORMATION

#### General Fluid and Cell Culture Sampling High Purity Sampling Units





Sample	Sampling	Needle		
Volume (mL)	Unit	Size (mm)	Qty/Pk	Catalogue No.
50	Single	1	50	1711-10050
100	Single	1	50	1711-10100
250	Single	1	50	1711-10250
1000	Single	1	50	1711-11000
5 x 50	Multi	1	5	1714-10050
5 x 100	Multi	1	5	1714-10100
5 x 250	Multi	1	5	1714-10250
50	Single	2	50	2711-10050
100	Single	2	50	2711-10100
250	Single	2	50	2711-10250
1000	Single	2	50	2711-11000
5 x 50	Multi	2	5	2714-10050
5 x 100	Multi	2	5	2714-10100
5 x 250	Multi	2	5	2714-10250

#### **ORDERING INFORMATION (CONTINUED)**

#### General Fluid and Cell Culture Sampling High Purity Eyeball Bag







Sample	Sampling	Needle		
Volume (mL)	Unit	Size (mm)	Qty/Pk	Catalogue No.
100	Single	1	50	1111-00001
5 x 100	Multi	1	5	1113-00002
100	Single	2	50	2111-00008
5 x 100	Multi	2	5	2113-00009

#### Autoclavable Units

Sample Volume (mL)	Sampling Unit	Needle Size (mm)	Qty/Pk	Catalogue No.
50	Single	1	50	1221-60050
100	Single	1	50	1221-60100
250	Single	1	50	1221-60250
1000	Single	1	50	1221-61000
50	Single	2	50	2221-60050
100	Single	2	50	2221-60100
250	Single	2	50	2221-60250
1000	Single	2	50	2221-61000

#### Accurate Volume Sampling Units

Sample Volume (mL)	Sampling Unit	Needle Size (mm)	Qty/Pk	Catalogue No.
5	Single	1	50	1421-50005
5 x 5	Multi	1	5	1424-50005
20	Single	1	40	1421-50020
5 x 20	Multi	1	5	1424-50020
5	Single	2	50	2421-50005
5 x 5	Multi	2	5	2424-50005
20	Single	2	40	2421-50020
5 x 20	Multi	2	5	2424-50020



# NovaSeptum Sterile Sampling Systems

#### ORDERING INFORMATION



Volume (mL)	Needle Size (mm)	Tubing	Tubing Connector	Qty/Pk	Catalogue No.
250	1	—	—	50	3711-30250
_	1	500 mm Polyethylene	3-piece Luer	50	3511-10014
_	1	500 mm Silicone	3-piece Luer	50	3521-10014
250	2	_		50	4711-40250
_	2	500 mm Polyethylene	3-piece Luer	50	4511-10014
_	2	500 mm Silicone	3-piece Luer	50	4521-10014

#### NovaSeptum Holders







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#### TC Holder

Transfer Units

Sampling Type	No. of Sample Ports	TC Size (0.D. Ø)*	Catalogue No.
General	1	25 mm (1/2 in.)	AT11/2-310
	5	50.5 mm (1 1/2 in.)	AT51/5-310
	9	64 mm (2 in.)	AT91/6-310
Cell Culture	1	25 mm (1/2 in.)	AT12/2-310
	5	50.5 mm (1 1/2 in.)	AT52/5-310
	9	64 mm (2 in.)	AT92/6-310

#### Ingold Holder

Sampling Type	No. of Sample Ports	Ingold Ferrule	Catalogue No.
General	2	25 mm	AG21/380x252-310
Cell Culture	2	25 mm	AG22/380x252-310

#### In-line TC Holder

Sampling Type	No. of Sample Ports	Tube Size (O.D. Ø)*	TC Size (0.D. Ø)*	Catalogue No.
General	1	1/2 in. (ASTM)	25 mm (1/2 in.)	AP11/127x94-312
		3/4 in. (ASTM)	25 mm (1/2 in.)	AP11/191x158-312
		13 mm (DIN)	25 mm (1/2 in.)	AP11/130x100-312
		19 mm (DIN)	25 mm (1/2 in.)	AP11/190x160-312
Cell Culture	e 1	1/2 in. (ASTM)	25 mm (1/2 in.)	AP12/127x94-312
		3/4 in. (ASTM)	25 mm (1/2 in.)	AP12/191x158-312
		13 mm (DIN)	25 mm (1/2 in.)	AP12/130x100-312
		19 mm (DIN)	25 mm (1/2 in.)	AP12/190x160-312

#### ORDERING INFORMATION (CONTINUED)

#### NovaSeptum Holders



In-line Butt-end Holder

Sampling Type	No. of Sample Ports	Tube Size (0.D. Ø)*	Catalogue No.
General	1	1/2 in. (ASTM)	AP11/127x94-311
		3/4 in. (ASTM)	AP11/191x158-311
		13 mm (DIN)	AP11/130x100-311
		19 mm (DIN)	AP11/190x160-311
Cell Culture	1	1/2 in. (ASTM)	AP12/127x94-311
		3/4 in. (ASTM)	AP12/191x158-311
		13 mm (DIN)	AP12/130x100-311
		19 mm (DIN)	AP12/190x160-311

\* Other sizes available on request.

NOTE: Holders require NovAseptic "NA Connect" fittings. For additional information, please refer to the **NovAseptic Hardware** section.

#### Fully Adjustable Bag Racks

Sampling Units	Fits NovaSeptum Holder	Catalogue No.
For single sampling units	1-port holder, TC25 in-line	A001
	1-port holder, TC 25/NAC 18	A002
	5-port holder, TC 50.5	A003
	9-port holder, TC 64	A004
	Ingold holder	A005
For multi-sampling units	1-port holder, TC 25/NAC 18	A006
	1-port holder, TC25 in-line	A007
	5-port holder, TC 50.5	A008
	9-port holder, TC 64	A009
	Ingold holder	A010

#### Accessories

	Sampling Type	Qty/Pk	Catalogue No.
Manual Crimping Tool		1	A100
Manual Crimping Tool Spare Part Kit	—	1	A101

Sampling Units	Sampling Type	Qty/Pk	Catalogue No.
NovaSeptum Port Plugs	General sampling	100	A201
	Cell culture sampling	100	A202





NovaSeptum bag racks are available for single and multi-sampling units

#### Manual Crimping Tool



The manual crimping tool enables a safe, secure cut without risk of contamination.

# Microbial Monitoring Solutions



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Milliflex Rapid Microbiology Detection and	
Enumeration System	457

#### **Milliflex PLUS Vacuum Pump** High-throughput Filtration System for Bioburden and Water Quality Testing



#### BENEFITS

- Automatic, hands-off filtration reduces testing time
- Sanitary design with autoclaveable pump heads
- Modular pump head provides filtration device flexibility
- Internal calibration program ensures
   accuracy

The compact Milliflex PLUS vacuum pump streamlines filtration steps during testing to accelerate QC sampling. When used with convenient Milliflex filtration funnels, the pump and Milliflex units comprise an integrated solution for delivering reliable, accurate results.

#### Easy to Use

By following simple text prompts that appear in the display window, operators easily and quickly perform IQ and OQ validation and set filtration cycles. For routine sampling, pre-loaded testing programs control the pump through all of the filtration steps automatically. With fluids that require special handling, such as antibiotics or other viscous liquids, a manual mode allows users to customize pump cycles to suit each SOP (standard operating procedure). The pump's small footprint suits tight workspaces and its low profile allows easy access in laminar flow hoods, so filtration can be performed almost anywhere.

#### High Throughput Testing

Built-in electronics ensure high productivity. In the automatic mode, filtration starts as soon as the specified sample volume is poured into the funnel and stops after the desired volume has been processed. Vacuum release and dry cycles automatically finish the filtration without requiring any action from the operator.

Sanitization is easy, so there's minimal disruption to workflow. For even greater throughput, a high-volume workstation of up to three Milliflex PLUS pumps can be set-up and used by a single operator. Testing reveals 3 Milliflex PLUS pumps are faster than a 6-place manifold.

#### **Consistent Results and Traceability**

A unique fluid management system ensures optimal performance and reproducible results. All system components in contact with the sample are either autoclavable or packaged pre-sterilized to ensure the cleanest possible operation for dependable results. An automatic dry cycle removes residual liquid so cross-contamination is eliminated. Its internal, weight-based calibration system measures and processes samples of equal volume to ensure consistency. Volume is displayed on the control keypad. The pump connects to a printer, allowing all relevant data to be tracked and downloaded for easy report generation after filtration.

#### Flexibility to Suit All Applications

When testing requirements change, we offer autoclavable pump head adapters for Millipore Sterisure<sup>™</sup> and MicropreSure filter units for added flexibility. Simply lift off the standard pump head and replace it with the one that fits the device.

#### Validation and Maintenance Services

Comprehensive validation protocols and on-site validation engineers are available to make validation faster and easier. Method development services are also available to set up efficient and simple test procedures for your specific samples. To ensure that your system's performance remains compliant with Millipore's validated specifications, Millipore offers a comprehensive range of maintenance contracts. For additional information, please refer to our Access Services section under Process Monitoring.

#### SPECIFICATIONS

#### Materials of Construction

Frame:	Polyester with 30% glass fiber
Key pad including display:	Polyester
Sleeve protector:	Polyester
Dimensions	
Height without head:	130 mm (5 in.)
Height with head:	135 mm (5.23 in.)
Width:	170 mm (6.69 in.)
Depth:	270 mm (10.6 in.)
Weight without head:	2.65 kg (5.84 lb)
Weight with head:	3.60 kg (7.91 lb)

PROCESS MONITORING

# Milliflex PLUS Vacuum Pump

#### SPECIFICATIONS (CONTINUED)

Power	24 Vdc, 25 W
Sanitization	
External surface:	Alcohol wipe
Internal surface:	Bleach 250 ppm, Peracetic acid 0.125%, Quaternary ammonium
Regulatory Compliance	CE mark
Milliflex PLUS Pump Adapters	
Material:	Stainless steel 316L
Sanitization:	Autoclave

#### ORDERING INFORMATION

Description	Qty/Pk	Catalogue No.
Milliflex PLUS Pump		
Milliflex PLUS pump single head kit	1	MXPP LUS 01
Milliflex PLUS pump double head kit	1	MXPP LUS 02
Milliflex PLUS pump triple head kit	1	MXPP LUS 03
Milliflex PLUS Adapters		
MSOpener <sup>™</sup> head for Milliflex PLUS pump	1	MSPH EAD 01
Sterisure head	1	MSTH EAD 01
Microfil V/S head	1	MCCH EAD 01
Microfil head	1	MCLH EAD 01
Milliflex PLUS Pump Accessories		
Additional Milliflex pump head	1	MXPH EAD 01
Milliflex PLUS pump	1	MXPP UMP 01
Milliflex PLUS printer	1	MXPR INT 01
Milliflex PLUS printer battery	1	MXPP BAT 01
Printer expendables, includes 5 rolls of thermal paper	1	ATBP RNT 22
Manifold tray for 2 Milliflex PLUS pumps	1	MXPP TRY 02
Manifold tray for 3 Milliflex PLUS pumps	1	MXPP TRY 03
Power supply for 1 Milliflex PLUS pump	1	MXPP 0WR 01
Power supply for 2 or 3 Milliflex PLUS pumps or Milliflex Rapid AutoSpray Station	1	MXPP 0WR 02
Sleeve protector for 1 Milliflex PLUS pump	2	MXPP SLS 01
Sleeve protector for 2 Milliflex PLUS pumps	2	MXPP SLS 02
Sleeve protector for 3 Milliflex PLUS pumps	2	MXPP SLS 03
Milliflex vacuum gauge pump	1	MXPT EST 01
Drain tubing	1	MXPP TUB E1
Pump head cover, white	1	MXPP LID 01
Validation Protocols		
Milliflex PLUS pump validation protocol (European A4 format)		MXPP A4V P1
Milliflex PLUS pump validation protocol (US letter format)		MXPP LTV P1

Milliflex PLUS pump validation protocol (US letter format)

Method development, installation, validation and maintenance services are available. Please refer to the Access Services section under Process Monitoring.

# **Milliflex Filter Unit**

## Ready-to-use, Sterile Milliflex Filter Units Combine a Funnel and a Gridded Membrane Filter in One Device



#### BENEFITS

- · Complete range of agar-based media
- · Sealed integral membrane filter eliminates membrane manipulation
- Faster filtration
- · Easy to maintain

#### Choice of Long-Life Media

A complete range of agar-based media in ready-to-use cassettes manufactured and QC tested according to pharmaceutical requirements. Their long shelf life enables the purchase of larger lot sizes, reducing the number of incoming QC tests needed.

#### More Reliable Results

A sealed integral membrane filter eliminates membrane manipulation and handling. This minimizes a major source of contamination and improves testing reliability. The sealed membrane avoids the bypass phenomenon often found with other filtration systems.

#### **Faster Filtration**

Up to twice the surface area of standard 47 mm membranes when used with a Microfil funnel.

#### We Are Ready When You Need Us

MicroSafe Biosafety Solutions Laboratory, Europe, our GMP/GLP compliant Contract Laboratory, is your solution for outsourcing your Milliflex tests.

For additional information, please refer to our Access Services section under **Process Monitoring.** 

#### Unique Break-Off Funnel

After filtration, funnel is detached without tools from membrane-containing part of the unit.

#### **Consistent Recoveries**

The convex shape of the membrane after filtration demonstrates the integrity of the membrane and avoids air bubble trapping when placed on culture media.

#### Simplified Colony Counting

Accurate counting is accomplished through a clear, condensation-free window in the cover of the culture cassette.

#### Easy to Maintain

Milliflex units are disposable and the Milliflex vacuum filtration system can be easily sanitized.

#### **Meets Regulatory Requirements**

The Milliflex system complies with worldwide pharmacopeias (Europe, US and Japan).

#### SPECIFICATIONS

#### Materials of Construction

Μ

Membrane:	Mixed esters of cellulose or Durapore membrane (Hydrophilic polyvinylidene fluoride, PVDF)
Funnel:	Polyethylene
Media Cassettes:	SAN
Filtration Area	17.3 cm <sup>2</sup>
Sample Volume	100 mL, 250 mL

#### **ORDERING INFORMATION**

Milliflex Filter Funnel Unit, 100 mL funnel, Sterile

Pore					
Size, µm	Filter Material	Color	Surface	Qty/Pk	Catalogue No.
0.45	Mixed esters of cellulose	white	gridded	24	MXHA WG1 24
0.45	Mixed esters of cellulose	black	gridded	24	MXHA BG1 24
0.45	Mixed esters of cellulose	white	gridded	24	MXHA WG1 LS*
0.45	Hydrophilic PVDF	white	plain	24	MXHV WP1 24
0.22	Mixed esters of cellulose	white	gridded	24	MXGS WG1 24
Milliflex Filter Funnel Unit, 250 mL funnel, Sterile					

0.45 µm	Mixed esters of cellulose	white	gridded	24	MXHA WG2 24

#### **Empty Media Cassette**

Description	Sterility	Qty/Pk	Catalogue No.
Milliflex—100 liquid media cassette	sterile	120	MXLM C01 20
Milliflex—100 solid media cassette	sterile	120	MXSM C01 20
Manifold Filter Support			
Description		Qty/Pk	Catalogue No.
Milliflex SST filter support for manifold		1	MXAC 000 01

\* Individually packaged, each package contains 1 Milliflex unit and 1 liquid media cassette.



## **Prefilled Milliflex Cassettes** A Full Range of Solid Media for Bioburden Testing



Milliflex filter funnel units can be used in conjunction with either liquid media or agar cassettes.

# Nothing to Prepare, Nothing to Clean Up

Preparing your own agar cassettes may seem like a way to save money, until you consider the high cost of labor, materials and quality control. This is why many Milliflex system customers favor prefilled agar cassettes.

#### Ready When You Are

Another reason many customers prefer Milliflex agar cassettes is shelf life. With today's tight lab budgets, you don't want to waste media. Our high purity ingredients and ISO<sup>®</sup>-certified manufacturing processes give Milliflex media a longer shelf life than formulations that are prepared on-site.

#### On-Line Help with Dr. Media

Our Dr. Media On-Line Help provides a photo and detailed descriptions of typical colony morphology for every agar product for easy identification.

For additional information visit: http://www.millipore.com/drmedia

#### BENEFITS

- Save time and labor
- QC tested for product release
- Complies with regulatory requirements world-wide

#### ORDERING INFORMATION

#### 48 cassettes/Pk

Media	Target Microorganisms	Catalogue No.
Baird parker agar	Staphylococcus species	MXSM BPA 48
Cetrimide agar	Pseudomonas aeruginosa	MXSM CET 48
Heterotrophic plate count agar	Heterotrophic microorganisms	MXSM HPC 48
KF strep agar	Fecal streptococci	MXSM KFS 48
Manitol Salt agar	Staphylococcus species	MXSM MSA 48
m-Endo LES agar	Coliform organisms	MXSM END 48
Plate count agar	Total aerobic microorganisms	MXSM PCA 48
Pseudomonas isolation agar	Pseudomonas species	MXSM PIA 48
R2A agar	Heterotrophic bacteria in a stressed environment	MXSM CRA 48
Sabouraud dextrose agar	Yeast and mold	MXSM CSD 48
Sabouraud with chloramphenicol	Yeast and mold	MXSM CSP 48
Tryptone glucose extract agar	Heterotrophic microorganisms	MXSM TGE 48
Tryptic soy agar	Heterotrophic microorganisms	MXSM CTS 48
Tryptic soy agar with poly 80 and lecithin	Heterotrophic microorganisms	MXSM TLP 48
Yeast and mold agar	Yeast and mold	MXSM CYM 48
24 cassettes/Pk		
Cetrimide with naladixic acid	Pseudomonas aeruginosa	MXSM CET 24
MacConkey agar	Lactose fermenting bacteria and coliforms	MXSM CMC 24

For additional information on liquid media, please refer to page 512.

# MilliSnap System

# An Automated System to Detach the Milliflex Funnel While Connecting the Membrane to the Media Cassette



#### BENEFITS

- Easy to handle
- · Fully automated
- Portable
- Compatible with all Milliflex funnels and media cassettes

Designed to simplify your workflow, the MilliSnap plug and play system is a hands-free method for separating your Milliflex funnel and attaching the membrane to the Millipore media cassettes. The unique convex shape of the Milliflex membrane combined with the MilliSnap system ensures proper contact between membrane and media.

What's more, the small footprint of the MilliSnap system makes it ideally suited for the busy lab bench. Its low operation area allows for easy access in both laminar flow hoods and safety cabinets, enabling operators to quickly and efficiently snap the funnel from the media cassette.

# Remove Your Milliflex Funnel in a Snap

Breaking off the Milliflex funnel has never been easier. Simply place the membrane on the media, insert your unit into the MilliSnap system and close the safety glass. Using pressure, the MilliSnap system automatically separates the funnel from the membrane cassette. Once complete, you can easily remove the broken funnel and begin the incubation. For the ultimate convenience and efficiency, combine the Milliflex PLUS pump with the MilliSnap automated system. After utilizing the Milliflex PLUS Pump during the filtration step, simply introduce the funnels and the media cassettes into the MilliSnap system.

#### SPECIFICATIONS

#### **Materials of Construction**

Housing:	Polyurethane
Frame:	304L stainless steel and epoxy paint
Safety glass:	Polycarbonate
Safety glass handle:	304L stainless steel
LED protector:	Polycarbonate
Adapters:	Polyoxymethylene (POM)
Adapter gasket:	Ethylene propylene diene monomer (EPDM)
Feet:	Polyvinyl Chloride (PVC)
Front sticker:	Polyesther
Dimensions	
Length:	200 mm (7.87 in.)
Width:	190 mm (7.48 in.)
Height:	335 mm (13.18 in.)
Weight:	7.7 kg (17 lb)
Power	
Supply voltage:	100 V – 240 V (50 Hz – 60 Hz)
Nominal consumption:	36 W
Peak state consumption:	300 W
Sanitization	
External/internal surfaces:	Alcohol wipe
Adapters:	Autoclave or alcohol wipe

#### **Regulatory Compliance**

The MilliSnap system complies with EU Directive 89/336/EEC on electromagnetic compatibility, as attested by the CE mark.

#### ORDERING INFORMATION

#### MilliSnap System

Description	Qty/Pk	Catalogue No.
MilliSnap System	1	MIL SNAP 01
MilliSnap Kits		
MilliSnap system and Milliflex PLUS pump single head	1	MFX SNAP 01

# MilliSnap System

#### ORDERING INFORMATION (CONTINUED)

Description	Qty/Pk	Catalogue No.
MilliSnap Kits		
MilliSnap system and Milliflex PLUS pump double head	1	MFX SNAP 02
MilliSnap system and Milliflex PLUS pump triple head	1	MFX SNAP 03
MilliSnap System Accessory		
MilliSnap system protective glass	1	MSGLASS 01
NilliShan System Adaptara		
MilliShan system 100 mL funnel adapter for incubation on solid media cassette	1	MSSM 100 01
MilliSnap system 250 mL funnel adapter for incubation on solid media cassette	1	MSSM 250 01
MilliSnap system 100 mL funnel adapter for incubation on liquid media cassette	1	MSLM 100 01
MilliSnap system 250 mL funnel adapter for incubation on liquid media cassette	1	MSLM 250 01
Milliflex PLUS Pumps and Accessories		
Milliflex PLUS pump, single bead kit	1	MXPP LUS 01
Milliflex PLUS pump, double head kit	1	MXPP LUS 02
Milliflex PLUS pump, triple head kit	1	MXPP LUS 03
Millifley DLUS Dump Accessories		
Additional Milliflay bood	1	
	1	
	1	
Manifold tray for 2 pumps	1	MXPP TRY 02
Manifold tray for 3 pumps	1	MXPP TRY 03
Power supply for 1 pump	1	MXPP 0WR 01
Power supply for 2 or 3 pumps	1	MXPP 0WR 02
Sleeve protector for 1 pump	2	MXPP SLS 01
Sleeve protector for 2 pumps	2	MXPP SLS 02
Sleeve protector for 3 pumps	2	MXPP SLS 03
Milliflex Expendables		
Milliflex filter funnel unit 100 ml sterilized and packed		
0.45 µm MCF white gridded membrane	24	MXHA WG1 24
0.45 µm MCE black gridded membrane	24	MXHA BG1 24
0.45 µm PVDF white plain membrane	24	MXHV WP1 24
0.22 µm MCE white gridded membrane	24	MXGS WG1 24
Millifley filter funnel unit 250 ml. sterile		
0.45 um MCE white gridded membrane	24	MXHA WG2 24
	LT	
P2A Ager	49	
	40	
Plate Count Agar	40	
	48	
Sabouraud Chloramphenicol Agar	48	MXSM CSP 48
Sabouraud Dextrose Agar	48	MXSM CSD 48
MacConkey Agar	24	MXSM CMC 24
Baird Parker Agar	48	MXSM BPA 48
m-Endo Agar	48	MXSM END 48
TGE Agar	48	MXSM TGE 48
Services		
Validation and Maintenance Services		Contact Millipore

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### **Milliflex Rapid Microbiology Detection and Enumeration System** An Automated System for Rapid, Accurate Detection and Enumeration of Microorganisms



#### BENEFITS

- CFU test results correlate with traditional methods
- · Easy to operate and validate
- Results in approximately one-fourth of the time of membrane filtration or pour plate methods



Conventional (left) vs. Milliflex Rapid Image Analysis (right)

The Milliflex Rapid Microbiology Detection and Enumeration system is an automated solution for the rapid detection, response, and resolution of microbial contamination in filterable samples throughout the manufacturing process. The system improves process control, product yield and the timely release of products. Based on Adenosine Triphosphate (ATP) Bioluminescence technology, the Milliflex Rapid system delivers faster test results than traditional microbial contamination detection methods, such as membrane filtration (MF) and pour plates. The Milliflex Sample Prep method also ensures consistent, reliable results. The Milliflex Rapid system can clearly distinguish between mixed microbial growth of slow growing and fast growing microorganisms, as well as variances in their size and ATP content in water samples.

#### Results in Hours, Not Days

Detect bacteria in approximately 1/4 the time of your current method. The Milliflex Rapid system can detect and count viable microorganisms filtered onto a membrane down to 1 CFU per sample. The software displays results as familiar colony forming units (CFU) therefore providing a direct comparison with historical data obtained from traditional methods.

#### **Three Proven Technologies**

The Milliflex Rapid system uses proven technologies including membrane filtration, ATP bioluminescence and image analysis for ease of validation.

- 1. Membrane Filtration Today's standard for sample preparation. Large volumes of product can be processed and any inhibitor substances are easily rinsed away.
- 2. ATP Bioluminescence ATP (adenosine triphosphate) is a

proven indicator of cell viability.

3. Image Analysis for Enumeration of Microorganisms

The concentration of ATP required for measurement is about 200 attomoles, which is equivalent to one yeast or mold cell or approximately 100 bacterial cells, depending on their metabolic state. The sensitivity of the reagents combined with a charged coupled device (CCD) camera and image processor requires only a short incubation period to generate enough ATP for detection and enumeration.

The system captures the light signals emitted from the microorganisms on the membrane with a CCD camera. The image analysis software intensifies the bioluminescence from each cell (or micro-colony) thousands of times and an image processor enumerates the microorganisms and displays them on a computer screen.

#### Automated Image Analysis

The technologically advanced Milliflex Rapid Image Analysis software enables analysts to test water, in-process products, raw materials and final products in a fraction of the time of traditional methods.

Access and editorial privileges are controlled by the system administrator ensuring secure data acquisition and retrieval.

The detection tower scans and develops an image of the microcolonies on the membrane.

The system counts each microcolony and stores the data for downloading, printing and retrieval. Within approximately two minutes, the sample analysis and results are displayed along with the batch history and electronic image of the membrane with results displayed in familiar colony forming units (CFUs), which can also be viewed three dimensionally. Batch history allows analysts to identify trends at a glance and the electronic images confirm test results.

#### 21 CFR Part 11 Compliance Ready

Milliflex Rapid Microbiology Detection and Enumeration software meets the requirements of FDA Regulation 21 CFR Part 11 for Electronic Records and Electronic Signatures. The software's powerful batch reporting feature meets the technological requirements of FDA's 21 CFR Part 11 for Electronic Signatures and Electronic Batch Reporting. The batch reporting feature includes capabilities for electronic signing, performing audit trails and rendering data files unalterable.

#### **Milliflex Rapid AutoSpray Station** For the Application of Bioluminescent Reagents onto Membranes



#### BENEFITS

- Consistent performance delivers reproducible results
- · Automated operation for ease of use
- Two spray nebulizers per station for quick application of both reagents
- Used with the Milliflex Rapid Microbiology Detection and Enumeration System

An integral component in the Milliflex Rapid Microbiology Detection and Enumeration System, the Milliflex Rapid AutoSpray Station applies an equal volume of two reagents across a membrane surface in order to detect living microorganisms.

Using a proven, pre-set automated program, the AutoSpray Station ensures reproducible results, test after test. Reagent application is achieved using a back and forth sweeping movement of the filter holder under the calibrated glass nebulizer.

#### **Streamlined Operation**

In automatic spray mode, the AutoSpray Station delivers both reagents in 90 seconds at the touch of a button. From the control panel, analysts can easily initiate an operation by selecting from a list of operations.

#### Easy to Clean and Maintain

The AutoSpray Station issues a warning message across the control panel when calibration, cleaning or priming are required, ensuring consistent and reliable performance throughout the life of the system.

A self-cleaning unit, the AutoSpray Station is ready for re-use in five minutes. The unit should be recalibrated after every 5000 samples, or at least once a year.

#### Validation and Maintenance Services

Comprehensive validation protocols and on-site validation engineers are available to make validation faster and easier. Method development services are also available to set up efficient and simple test procedures for your specific samples. To ensure that your system's performance remains compliant with Millipore's validated specifications, Millipore offers a comprehensive range of maintenance contracts. For additional information, please refer to our Access Services section under Process Monitoring.

#### References

1 FDA draft guidance for industry, "PAT – A Framework for Innovative Pharmaceutical Manufacturing and Quality Assurance", September 2004.

2 FDA/OPS meeting, April 13, 2004, pages 104 – 110, 136.

3 PDA. May/June 2000. Technical Report No. 33: Evaluation, Validation and Implementation of New Microbiological Testing Methods. PDA Journal of Pharmaceutical Science and Technology 54(3) Supplement TR33.

Microbial Monitoring Solutions

#### SPECIFICATIONS

#### Milliflex Rapid Microbiology Detection and Enumeration System

Detection Area	Within the area of the 5	5 mm diameter Millifl	ex membrane			
Sensitivity of System	1 CFU/Sample	1 CFU/Sample				
PC Configuration	PC with Windows XP® F screen resolution (120 c and PCI full size mounti	Professional operating lpi), 19 in. monitor, 1 ng for image board.	g system and 256 M .3 GHz processor sp	B memory, 1280 x 1024 eed and 40 GB hard drive		
Dimensions and Weight						
	Width cm (in.)	Depth cm (in.)	Height cm (in.)	Weight kg (lb)		
Detection Tower						
	20 (8)	20 (8)	31 (12)	6 (13)		
Image Intensifier Controller						
	23 (9)	34 (13)	8 (3)	3 (7)		
PC	18 (7)	45 (18)	43 (17)			
Electrical						
Power Supply:	110 V, 60 Hz or 230 V, 50 Hz					
Consumption:	30 W					

#### ORDERING INFORMATION

Description	Voltage	Qty/Pk	Catalogue No.
Milliflex Rapid Microbiology Detection and Enumeration System Kit	110 V/230 V	1	MXRP KT1 10
Includes: Detection tower, Image analyzer, CCD camera, AutoSpray station, removal tool, PC with image board and software			
Milliflex Rapid AutoSpray Station	110 V/230 V	1	MXRP SPR KT
Includes: AutoSpray station, filter holder, pad holder, nebulizer cleaner, 5 mL female Luer syringe, 3 nebulizers, silicone liquid tubes, 2 stainless steel caps and universal power supply adaptor			
Milliflex PLUS Pump			
Single head kit	N/A	1	MXPP LUS 01
Double head kit	N/A	1	MXPP LUS 02
Triple head kit	N/A	1	MXPP LUS 03
Milliflex Rapid Funnel 0.45 µm PVDF Membrane	N/A	24	RMHV MFX 24
Milliflex Rapid Reagent Kit for 100 tests	N/A	1	MXRP BLR ST
ATP releasing agent, 2 bottles			
Bioluminescent reagent, 2 bottles			
Reconstitution buffer, sterile, 2 bottles			
2 syringes, 5 Luer-Lok <sup>®</sup> caps, and 6 vial adapters			



# Milliflex Rapid AutoSpray Station

#### SPECIFICATIONS

#### Milliflex Rapid AutoSpray Station

#### Materials of Construction

Turntable, Pad holder, Membrane holder:	316L stainless steel
Cover and Casing:	Polyurethane
Keypad:	Polyester
Dimensions and Weight	
Width:	21 cm (8 in.)
Depth:	40 cm (16 in.)
Height:	31 cm (12 (in.)
Weight:	10 kg (22 lb)
Electrical	
Power Supply:	110 V or 230 V
Consumption:	30 W
Operational Requirements	
Ambient Temperature:	15 – 40 °C
Relative humidity:	< 90%
Altitude:	< 3000 m (9842 ft)
The AutoSpray Station can be used under a laminar flow hood	
Regulatory Information	The AutoSpray Station is compliant with Electromagnetic Compatibility Directive 89/336/EEC and is CE marked.

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#### **ORDERING INFORMATION (CONTINUED)**

Description	Qty/Pk	Catalogue No.
Milliflex Rapid Cleaning/Decontamination Kit	1	MXRP CLK T1
For 20 cleanings, 2 decontaminations		
Rinsing agent, 4 bottles		
Cleaning agent, 4 bottles		
Decontamination agent, 1 bottle		
10 Luer-Lok caps, 9 vial adapters		
Cover cap for vial holder	1	MXRP C0V ER
Cover cap for vial holder	1	MXRP C0V ER
Filter Holder	1	MXRP SPF H1
Glass Nebulizer	1	MXRP GLA SS
Pad Holder	1	MXRP SPP H1
Power Supply for 2 or 3 Milliflex PLUS Pumps or Milliflex Rapid AutoSpray Station	1	MXPP 0WR 02
Millex®-FG 0.2 µm hydrophobic PTFE 25 mm filter PVC Ethylene Oxyde Sterilized	50	SLFG 025 LS
Pad Dispenser with a canister of 100 Absorbent Pads	2	AP10 045 S1
Nebulizer cleaner (svringe)	1	MXRP NEB CL

#### Milliflex Rapid Validation Protocols

5 mL female syringe

Silicon liquid tube

Silicon air tube

Description	Format	Qty	Catalogue No.
Milliflex Rapid Microbiology Detection and Enumeration System Validation Protocol			
Includes: IQ & OQ for AutoSpray Station	A4	1	MXRP A4V P1
and Milliflex Rapid System	US Letter	1	MXRP LTV P1
Milliflex PLUS Pump Validation Protocol	A4	1	MXPP A4V P1
	US Letter	1	MXPP LTV P1

# *Mycoplasma* Detection



MilliPROBE Real-Time Detection System	I
for Mycoplasma	463
MTC-NI System	

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# Mycopla

# *Mycoplasma* Detection

# MilliPROBE Real-Time Detection System for Mycoplasma

### Real-Time TMA Technology for Fast, Sensitive, Reliable Culture-Free Microbial Detection



#### BENEFITS

- Specific detection of Mycoplasma
- Sample preparation method enables processing of 20 mL of bioreactor matrix
- Reduces processing risk and increases operational efficiency
- · Delivers sensitive, reliable results

#### TARGET APPLICATIONS

- Bioreactor monitoring
- · Raw material screening

MilliPROBE system is an in-process early warning system that will provide you with faster, more effective detection of *Mycoplasma*. It is the first system that combines both speed and sensitivity in one screening tool enabling you to detect any potential *Mycoplasma* contamination events earlier in your process. Real-time detection allows you the opportunity to perform any corrective action earlier in your production process significantly reducing downstream processing risks.

#### AN INNOVATIVE SOLUTION FOR MYCOPLASMA DETECTION

As a result of a collaboration between Millipore and Gen-Probe, the MilliPROBE system combines industry accepted, easy-to-use membrane filtration methodologies with advanced, proven nucleic acid technologies to deliver fast, sensitive and reliable microbial detection results in one solution.

Unlike traditional detection methods, the MilliPROBE system is completely culture-free. Instead it utilizes proprietary Target Capture and Real-Time Transcription-Mediated Amplification (TMA) technologies with Background Reduction Technology\*\* to concentrate, purify, and amplify ribosomal RNA (rRNA) for the detection of targeted microbial contamination. Multiple oligonucleotide sequence-specific steps are used to ensure that the intended specificity is achieved with every MilliPROBE test.

From sample prep to data analysis, the MilliPROBE system provides results within 5 hours yielding unmatched sensitivity for the detection of low levels of *Mycoplasma* contamination earlier in your process.

# A COMPLETE INTEGRATED SOLUTION

MilliPROBE sample processing consists of sample preparation, Target Capture, amplification and detection and automated data analysis. Each step is integrated to ensure a seamless, efficient process. All reagents are manufactured and quality controlled to meet MilliPROBE assay performance specifications.

#### Sample Preparation

Samples are processed using standard membrane filtration. A Lysis Reagent is added to the membrane and briefly incubated to release and stabilize any microbial rRNA before it is drawn through the membrane and collected for further processing.

\*\* Target Capture and Real-Time Transcription-Mediated Amplification (TMA) and Background Reduction Technology are technologies of Gen-Probe Incorporated.

#### MILLIPROBE REAL-TIME TMA FACTS

- No growth or pre-enrichment step required
- Targets rRNA
- Utilizes a single primer and two enzymes
  - Reverse transcriptase
  - T7 RNA polymerase
- Amplifies RNA to RNA via DNA intermediates
- Isothermal reaction (no thermal-cycler required)





# MilliPROBE Real-Time Detection System for Mycoplasma

#### SPECIFICATIONS

#### MilliPROBE System Components

Power Supply	120V/230V/100V, 50/60Hz	
Dimensions		
Height:	200 mm	
Width:	380 mm	
Depth:	505 mm	
Weight:	~ 20 kg	
Thermo Scientific KingFisher mL Instrument		
Power Supply	100 – 240V, 50/60Hz	
Dimensions		
Height:	300 mm	
Width:	300 mm	
Depth:	300 mm	
Weight:	~ 10 kg	
eppendorf Thermomixer R Workstation		
Power Supply	100 – 240V, 50/60Hz	
Dimensions		
Height:	12.5 cm	
Width:	22 cm	
Depth:	25 cm	
Weight:	~ 3.6 kg	

#### ORDERING INFORMATION

Description	Qty	Catalogue No.
MilliPROBE Instruments		
MilliPROBE Instrument Package (US)	1	GPINST0110
MilliPROBE Instrument Package (EU)	1	GPINST0220
PTI FluoDia T70 Microplate Reader		
Thermo Scientific KingFisher mL Instrument		
<ul> <li>eppendorf Thermomixer<sup>®</sup> R Workstation (with 96-well block and adapter plate)</li> </ul>		
<ul> <li>MilliPROBE Data Analysis Software*</li> </ul>		
MilliPROBE Sample Prep Rack		
MilliPROBE Start-up Consumables		
MilliPROBE System User Guide for Mycoplasma		
MilliPROBE Data Analysis Software User Guide		
MilliPROBE Reagents and Sample Prep Kit		
MilliPROBE Reagent Kit for Mycoplasma	90 tests	GPMYCS100
MilliPROBE 2 to 8 °C Reagents		
Enzyme Reagent		
<ul> <li>Enzyme Reconstitution Solution</li> </ul>		
Amplification Reagent		
<ul> <li>Amplification Reconstitution Solution</li> </ul>		
Positive Control		
<ul> <li>Sealing Cards (for 96-well plates)</li> </ul>		
MilliPROBE 15 to 30 °C Reagents		
Lysis Reagent		
Wash Reagent		
Target Capture Reagent		
Sample Prep Consumables		

\* Minimum Operating Requirements: PC with Microsoft<sup>®</sup> Windows XP<sup>®</sup> operating system, 256 MB memory, 1280 x 1024 screen resolution (120 dpi), large size fonts, 17 in. monitor (19 in. recommended), 1.3 GHz processing speed, and Microsoft's .NET Framework 3.0.

#### Mycoplasma Testing Services

MicroSafe Biosafety Solutions Laboratory, Europe, our GMP/GLP compliant Contract Laboratory, offers a broad range of standard and custom *mycoplasma* testing as well as *mycoplasma* Identification capabilities. We can also assemble a team of experienced scientists to design and set up the assays you need. For additional information, please refer to our **Access Services** section under **Process Monitoring**.

# **MTC-NI System** An Easy-to-use System for the Rapid Screening of *Mycoplasma*



#### BENEFITS

- Detection and analysis in only 75 minutes including 15 minutes of hands-on time
- Detects commonly occurring *Mycoplasma* species with a sensitivity of 10<sup>5</sup> microorganisms or higher
- Detection of multicopy rRNA using Gen-Probe Hybridization Protection Assay (HPA) technology to ensure sensitivity and robustness
- Ideal as a first line screening tool for broad spectrum detection of microorganisms
- Easy-to-use assay requiring minimal training

Mycoplasma (e.g microorganisms belonging to class Molicutes) contamination is a widespread and reoccurring problem in a wide variety of cell culture systems. These organisms are small (0.2 - 0.3 µm), lack a cell wall and are antibiotic tolerant. This allows them to grow to high titers without exhibiting typical bacterial contamination signs such as a change in turbidity, which traditional growth based methods can not detect. Current methods for positive detection of species belonging to this genus include plating onto agar and liquid co-cultures with VERO cells followed by DNA staining. Although these technologies yield sensitive and reliable results the time to result is typically 2 - 4 weeks.

#### MTC-NI Technology

The MTC-NI (*Myocplasma* Tissue Culture Non-Isotopic Rapid Detection) system utilizes the patented HPA assay format from Gen-Probe in which a labeled (acridinium ester) ssDNA probe, complimentary to a conserved region of the ribosomal RNA, is hybridized to the released rRNA of the target organisms. Upon probe binding to the target RNA, the acridinium esther is protected inside the newly formed double helix. After hybridization is completed (all DNA probes have found their target RNA), a selection reagent (0.6M Sodium borate) is added to the solution. The selection reagent hydrolyses unbound probes thus circumventing any signal generation from non-hybridized probes. During detection, the bound probes will produce chemiluminescence (induced by hydrogen peroxide from the detection reagent) that is detected by the LEADER® instrument. Signal is then presented as Relative Light Units (RLUs) where a positive signal is defined as a value above a certain threshold value.

The main advantage of this technology is the simplicity of the assay, both in terms of handling and assay components. Because the MTC-NI HPA assay uses a hybridization event followed by a non-enzymatic hydrolyses and detection, it is very tolerant to sample matrix variation and common inhibitors (Heparin, EDTA, etc), which might have a strong negative influence on other common NA detection methods.

#### MTC-NI WORKFLOW

#### Sample Preparation

- Centrifuge 1.5 mL tissue culture medium for 10 minutes
- Remove supernatant
- Add hybridization reagent
- Vortex to resuspend



- Transfer sample to probe tube
- Mix gently
- Incubate 45 minutes at 60 °C



- Add selection reagent, incubate 10 minutes at 60 °C
- Cool 5 minutes at room temperature
- Read in LEADER instrument

Total Time to Result = 75 minutes

#### **ORDERING INFORMATION**

Description		Qty/Pk	Catalogue No.
MTC-NI Kit		50 tests	4573
Probe reagent, 5 x 10 tubes			
Hybridization reagent, 1 x 15 mL			
Selection reagent, 1 x 20 mL			
Positive Control, 1 x 2.5 mL RNA			
Detection Reagent Kit		1200 tests	1791
Detection reagent I, 1 x 240 mL			
Detection reagent II, 1 x 240 mL			
Luminometers			
LEADER 50i instrument	115v	1	105194
	220v	1	3100i
Accessories			
Dry heat bath		1	2775
PACE <sup>®</sup> Reaction tubes		120	2065
Leader printer paper		1	1847
SysCheck reagent		1	1078
(Calibration check of LEADER 50i Instrument) 5 x 3 mL			

#### Mycoplasma Testing Services

MicroSafe Biosafety Solutions Laboratory, Europe, our GMP/GLP compliant Contract Laboratory, offers a broad range of standard and custom mycoplasma testing as well as mycoplasma Identification capabilities. We can also assemble a team of experienced scientists to design and set up the assays you need. For additional information, please refer to our Access Services section under Process Monitoring.



# Sterility Testing Solutions





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Sterility Test Media and Rinse Buffers	480
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PROCESS MONITORING

### **Steritest Equinox Pump** An Intelligent Liquid-transfer Pump for Sterility Testing



#### BENEFITS

- Automatic pump head for easy tubing loading
- Enables user to program and save custom procedures
- · Consistent, reliable performance

The Steritest Equinox transfer pump is a software controlled peristaltic pump used for the safe, uniform transfer of drug samples from various packaging formats through Millipore sterility testing devices. The Steritest Equinox pump and Steritest EZ devices deliver unmatched sterility testing consistency and reliability.

#### Steritest Equinox Pump for Laminar Flow Hoods

The Steritest Equinox pump for laminar flow hoods fits in both horizontal and vertical Class A/Class 100 laminar flow hoods. Its unique profile prevents undesirable air turbulence in the area where handling is performed, eliminating the risk of false positives.

#### Steritest Equinox Isofit Pump

The Isofit version of the Steritest Equinox pump family features a low profile, which improves the ergonomic fit in isolators. The lower profile maximizes the work area within the isolator, allowing for greater efficiency. The patented connection design of the isolator work table reduces the height of the Steritest Equinox Isofit pump by 10 cm (4 in.) compared to the previous Isolator version. This optimized overhead work area eliminates the need for operators to raise their forearms, which is a significant benefit during long sterility testing operations where operator focus is required. Work space conservation is critical in batch isolators in order to accommodate the need for material storage. The pump is designed with smooth edges and constructed of 316L stainless steel for optimal decontamination.

From a computer, standard operating procedures (SOPs) can be developed and transferred onto the Steritest Equinox pump.

Analysts can select either manual or automated mode. In manual mode, the Steritest Equinox pump will prompt the analyst to enter data at each step of the procedure. In automated mode, an analyst simply selects the appropriate SOP for the sample to test from the Steritest Equinox control panel. The Steritest Equinox pump will walk the analyst through each step, acting as a training guide, thereby supporting good manufacturing practices. The various steps in the procedure, corresponding pump speed and related information are displayed on the control panel, improving repeatability and reliability.

#### Fast and Reliable Sterility Testing Transfer System

Designed for use with Steritest EZ devices, the automatic pump head makes it easy to load and unload Steritest and Steritest EZ unit tubing and is equipped with a precision "stop control" for low volume sampling. A built-in timer enables analysts to pre-set the time required for the transfer of product into both canisters. This is critical for product exposed to the environment such as glass ampoules, where there is a risk of introducing non-sterile air into the canisters and generating false positives.

A pressure control system constantly monitors the pressure inside Steritest EZ canisters ensuring that the system is running within acceptable pressure limits at all times. An alarm informs the operator of any pressure increase above specifications.

An external foot switch operates the pump in either "continuous" or "two-way" operation mode.

Validation and Maintenance Services

Comprehensive validation protocols and on-site validation engineers are available to make validation faster and easier. Method development services are also available to set up efficient and simple test procedures for your specific samples. To ensure that your system's performance remains compliant with Millipore's validated specifications, Millipore offers a comprehensive range of maintenance contracts. For additional information, please refer to our Access Services section under Process Monitoring.

# Steritest Equinox Pump

#### SPECIFICATIONS

#### Steritest Equinox Pumps

#### Materials of Construction

Frame, Pump Head, Pump Head Cover,	
and Bottle Holder:	316L stainless steel
Keypad and Screen Window:	Polyester
Drain Tray:	Polyacetal
Tubing for Drain Tray:	Silicone
Operational Requirements	
Ambient Temperature:	15 to 40 °C
Relative humidity:	< 90%
Altitude:	< 3000 m (9842 ft)
Electrical Requirement:	115/230 V
Input to Pump from Power Supply	24 VDC, 150 W
Sterilization	Pump head cover, roller knob, bottle holder and drain tray may be autoclaved for 30 minutes at 121 °C or 10 minutes at 134 °C.
Canister	Compatible with Steritest, Sterisolutest®, Steridilutor and Steritest EZ canisters
Regulatory Information	The Steritest Equinox pump is compliant with Electromagnetic Compatibility Directive 89/336/EEC and is CE marked.

#### **Dimensions and Weight**

#### Steritest Equinox Pump for Laminar Flow Hoods

Width, cm (in.)	Depth, cm (in.)	Height, cm (in.)	Weight, kg (lb)
Pump: 35 (14)	Pump: 30 (12)	Pump: 25 (10)	Pump: 14 (31)
Pump Fully Equipped: 59 (23)	Pump Fully Equipped: 34 (13)	Pump Fully Equipped: 53 (21)	Pump Fully Equipped: 17 (37)

#### Steritest Equinox Isofit Pump for Isolators

Width, cm (in.)	Depth, cm (in.)	Height, cm (in.)	Weight, kg (lb)
Pump: 35 (14)	Pump: 32.2 (13)	Pump: 15.2 (6)	Pump: 18.5 (41)
Pump Fully Equipped: 58.5 (23)	Pump Fully Equipped: 40 (15.7)	Pump Fully Equipped: 43 (16.9)	Pump Fully Equipped: 22 (48.5)

#### **ORDERING INFORMATION**

#### Steritest Equinox Pump for Laminar Flow Hoods

Description		Catalogue NO.
Steritest Equinox pump for laminar flow hoods Includes: software, bottle holder, canister holder and power supply unit	1	TQNX LFH 01
Accessories		
Pressure control kit for Steritest Equinox Pump		TQ00 PSI 01
Footswitch		TQ00 FTS 01
Holder for Steridilutor vent with expansion chamber		TQ00 TEV 01
Ampoule breaker		TNTA C00 01

**PROCESS MONITORING** 

#### ORDERING INFORMATION (CONTINUED)

#### **Spare Parts**

Description	Qty/Pk	Catalogue No.
Diamond cutting file	1	TCA0 000 02
Ampoule breaker screw	1	TCA0 000 07
Drain tray without drain tube	1	TQ00 DTR 01
Drain tray cover	1	TQ00 DTC 01
Pump head cover	1	TQ00 PHC 01
Silicone tubing for drain tray	1	TCA0 000 04
Bottle holder	1	TQ00 BTL 01
Electrical connection kit	1	TQ00 ELK IT
Includes: Power supply box, power cord for Europe and North America		
Steritest Equinox Pump for Isolators		
Steritest Equinox Isofit Pump for Isolators	1	TQNX ISL 03
Includes: software, bottle holder, canister holder and power supply unit		
Accessories		
Pressure control kit for the Steritest Equinox pump		TQ00 PSI 01
Footswitch		TQ00 FTS 01
Holder for Steridilutor vent with expansion chamber		TQ00 TEV 01
Ampoule breaker		TNTA C00 01
Spare Parts		
Diamond cutting file	1	TCA0 000 02
Ampoule breaker screw	1	TCA0 000 07
Drain tray without drain tube	1	TQ00 DTR 01
Drain tray cover	1	TQ00 DTC 01
Pump head cover	1	TQ00 PHC 01
Silicone tubing for drain tray	1	TCA0 000 04
Bottle holder	1	TQ00 BTL 03
Electrical connection kit		TQ00 ELK IT
Includes: Power supply box, power cord for Europe and North America		
Roller button	1	TQ00 RBU 01
Flat seal	1	TQ00 FLS 03

#### Validation Protocols

	Qty/Pk	Format	Catalogue No.
Steritest Equinox Pump for laminar flow	1	A4	TQNX A4V P1
hoods and/or isolators validation protocol	1	US Letter	TQNX LTV P1

Millipore offers a range of services for this product including method development, installation, validation and maintenance. For additional information, please refer to our **Access Services** section under **Process Monitoring**.



#### **Steritest EZ and Steritest Sterility Testing Devices** Easy, Fast and Safe Sterility Testing Devices



Steritest EZ sterility testing devices are sterile and do not inhibit microbial growth. They are supplied individually blister packaged and ready for quick installation in the Steritest Equinox pump. Different canister materials, membrane types and adapters match the individual requirements of pharmaceu-

tical test product packaging or medical devices.

#### Steritest EZ Design

Steritest EZ devices incorporate the same materials of construction as the Steritest devices

while offering a number of ergonomic benefits. Winged caps allow for easier handling and the 850 mm tubing, which is marked for identification, simplifies set-up with ample room to perform the manipulations involved in sterility testing. Closing and re-opening the pre-installed clamps during testing is as simple as pressing down or releasing as necessary, reducing resting time. The innovative inlet design of Steritest EZ canister reduces foaming, enabling faster filtration. The unique needle adapters enable fast and easy manipulation of liquid drugs. Designed to fit the majority of drug containers, the risk of blockage while testing drugs in vials with a thick septa is significantly reduced. The ergonomic, non-skid design offers a firm grip for gloved operators, especially in isolators.

In addition, with the marked tubing, identifying the canisters during media transfer is easier. The winged red plugs offer more efficient and easier handling. The double-packed, gamma-sterilized testing devices ensure optimum cleanliness. Double packaging allows an operator to open the outer bag in a clean room and bring the cleanest possible package into a laminar flow hood or isolator environment. The tear primer on the outer bag allows an operator wearing gloves to open the bag without using scissors.

#### Stringent Quality Program

Devices are manufactured and validated to stringent quality standards in ISO<sup>®</sup> 9001-certified manufacturing facilities, which have been audited by numerous pharmaceutical and biotechnology customers. The quality program for Steritest EZ includes incoming material controls, in-process controls for every manufacturing step and performance and reliability controls for finished product. Each device is 100% tested for integrity and subjected to visual uniformity checks.

#### We Are Ready When You Need Us

MicroSafe Biosafety Solutions Laboratory, Europe, our GMP/GLP compliant contract laboratory, is your solution for outsourcing your sterility tests with the Steritest system. We can also provide you with DNA typing Identification of bacteria and fungi.

For additional information, please refer to our **Access Services** section under **Process Monitoring.** 

#### BENEFITS

- Improved clamps, winged red plugs and tubing identification for easy handling
- Inlet reduces foaming, enabling faster filtration
- Ergonomically designed needle adapter fits the majority of test containers while maintaining a closed concept system

**PROCESS MONITORING** 

Sterility Testing Solutions

# Steritest EZ Devices for Products without Antimicrobial Activity



#### Liquids in Ampoules

- · Blue canister base indicates mixed esters of cellulose membrane
- · Single needle adapter for easy access to ampoules
- · Separate vent needle for transfer of culture media or rinse buffer

#### ORDERING INFORMATION



Liquids in Ampoules	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA LA2 10
Steritest EZ device double packed	10	TZHA LA2 05



#### Liquids in Collapsible Bags

- · Blue canister base indicates mixed esters of cellulose membrane
- Single needle adapter for easy access • to collapsible bags Separate vent needle for transfer of

culture media or rinse buffer

**ORDERING INFORMATION** 

Liquids in Collapsible Bags	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA LA2 10
Steritest EZ device double packed	10	TZHA LA2 05



#### LVP in Glass Bottles

- · Blue canister base indicates mixed esters of cellulose membrane with optimized underdrain for high flow
- Vented needle adapter vents and transfers test product large volume containers with septa to Steritest EZ devices



#### **ORDERING INFORMATION**



LVP in Glass Bottles	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA LV2 10
Steritest EZ device double packed	10	TZHA LV2 05

# Steritest EZ Devices for Products without Antimicrobial Activity



#### SVP in Vials

- Blue canister base indicates mixed esters of cellulose membrane
- Small diameter double needle adapter for small vials with septa



#### **ORDERING INFORMATION**

SVP in Vials	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA SV2 10
Steritest EZ device double packed	10	TZHA SV2 05



# Medical Devices and Collapsible Bags with Luer Connection

- Blue canister base indicates mixed esters of cellulose membrane
- Three adapters provided; male Luer fitting, female Luer fitting or single needle allow connection to a variety of test devices
- Separate vent for transfer of culture media or rinse buffer
- Use with NovaSeptum sterile sampling devices

#### **ORDERING INFORMATION**

Medical Devices – Three Adapters	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA MD2 10



#### **Pre-filled Syringes**

- Blue canister base indicates mixed esters of cellulose membrane
- Adapter allows for sequential testing of syringe contents and needle surfaces

#### ORDERING INFORMATION

I

Prefilled Syringes	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA SY2 10

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## Steritest EZ Devices for Products without Antimicrobial Activity



#### Liquids in Plastic Containers

- Blue canister base indicates mixed esters of cellulose membrane
- Non-coring needle adapter with aperture on side of needle minimize blockage when piercing plastic containers
- Separate vent needle included for transfer of test product, culture media or rinse buffer

#### ORDERING INFORMATION



Liquids in Plastic Containers	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHA PC2 10



#### Soluble Powders in Ampoules

- Blue canister base indicates mixed esters of cellulose membrane
- Simultaneously dilutes and transfers test products to canister set
- Single needle for transfer into and out of ampoules

#### ORDERING INFORMATION



Soluble Powders in Ampoules	Qty/Pk	Catalogue No.
Sterisolutest EZ device	10	TZHA DA2 10



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Soluple	rowders	111	via	IS

- Blue canister base indicates mixed esters of cellulose membrane
- · Small diameter double needle adapter
- Simultaneously dissolves/dilutes the sample in sterile diluent and filters the resulting solutions for small vials with septa



Soluble Powders in Vials	Qty/Pk	Catalogue No.
Sterisolutest EZ device	10	TZHA DV2 10



## For Antibiotics and Products with Antimicrobial Agents\*



#### Liquids

- Red canister base indicates low adsorption Durapore membrane and specific drain design
- Single needle adapter and connections designed to reduce the risk of antimicrobial residuals
- · Separate vent needle



#### ORDERING INFORMATION

Liquids	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHV AB2 10
Recommended Accessories		
Sterile vent needles for safe transfer of liquid media	1	TZGV 033 25

#### **Powders and Superpotent Antibiotics**

- Red canister base indicates low adsorption Durapore membrane and specific drain design
- Tubing and needle assembly for antibiotics and products containing antimicrobial activity that require dilution or dissolution
- Used for pooling superpotent antibiotics, which reduces contact time with the filtration membrane.
- Contains vent with expansion chamber for dilution/dissolution
- Aseptically connects the diluent or dissolution fluid to the product container for dilution
- Diluted product subsequently filtered with Steritest EZ device (TZHV AB2 10).





#### ORDERING INFORMATION

Powders and Superpotent Antibiotics	Qty/Pk	Catalogue No.
Steridilutor EZ device	10	TZVC 000 10
Steritest EZ device	10	TZHV AB2 10
Recommended Accessories		
Steridilutor vial accessory	1	TA00 000 03
Sterile vent needles for safe transfer of liquid media	1	TZGV 033 25

\*Additional devices are available for products with antimicrobial agents. Please contact your local Millipore representative for more information.

## Steritest Devices for Emulsions or Viscous Products





#### LVP in Glass Bottles

- Yellow canister base indicates increased flow rate and throughput
- Reinforced mixed esters of cellulose membrane useful for filtration of viscous products, cell-based products and lipids
- Vented needle adapter vents and transfers test product from large volume containers with septa to Steritest EZ devices

#### **Sterisolutest Small Vials**

- Yellow canister base indicates increased flow rate and throughput
- Reinforced mixed esters of cellulose membrane useful for filtration of viscous products, cell-based products and lipids
- Simultaneously dissolves the sample in sterile diluent and filters the resulting solution

#### ORDERING INFORMATION





Large and Small Vials	Qty/Pk	Catalogue No.
Steritest device	10	TLAR EM2 10
Sterisolutest device	10	TDAR EM2 10

## Steritest EZ Devices for Increased Chemical Compatibility



## Solvents, Creams, Ointments and Veterinary Injectables

- Green canister base indicates increased chemical compatibility with solvents due to Durapore membrane and specific canister polymer (polyamide)
- Canister designed for testing products dissolved in solvents such as Isopropyl Myristate
- Canister connections and reinforced base structure provide better resistance to pressure
- Single needle adapter for products in vials or ampoules
- · Separate vent needle



#### ORDERING INFORMATION

Solvents, Creams, Ointments and	eams, Ointments and	
Veterinary Injectables	Qty/Pk	Catalogue No.
Steritest EZ device	10	TZHV SL2 10



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## **Steritest and Steritest EZ Accessories**



#### Steridilutor EZ for Vials

- Tubing and needle assembly for difficult to dissolve powders and for dilution of viscous products in vials
- To be used for difficult to dissolve powders, dilution and pooling of viscous products in vials as well as antibiotics to reduce the contact time with the filtration membrane
- Small diameter double needle connects test product to diluent
- Diluted product subsequently filtered with suitable Steritest EZ devices

#### ORDERING INFORMATION



Steridilutor EZ for Vials	Qty/Pk	Catalogue No.
Steridilutor EZ device without expansion chamber	10	TZV0 000 10
Steridilutor EZ device with expansion chamber	10	TZVC 000 10

#### Liquid Transfer Kit

- Tubing and needle assembly for transfer of liquids from ampoules to a diluent vial with septum
- Diluted products subsequently tested with suitable Steritest canister



Product Name	Qty/Pk	Catalogue No.
Liquid transfer kit	10	TZA0 000 10



## **Steritest EZ Accessories**



#### Steridilutor Vial Accessory for Steriterst Compact and Steritest Integral Pumps

- Rotating bottle clamp attaches to Steritest pump bottle support stand
- Used for inverting diluent bottles
- Includes the expansion chamber holder

#### ORDERING INFORMATION

Product Name	Qty/Pk	Catalogue No.
Steridilutor vial accessory	1	TA00 000 03



#### Steritest Vent with Needle

- Single needle vented with PVDF 0.22 µm membrane
- For venting glass vials with rubber septa and rigid plastic vials
- For rinsing medical devices or for vial-to-vial aseptic transfer of large volume parenterals
- For venting of media bottles during the direct inoculation method

Product Name	Qty/Pk	Catalogue No.
Steritest vent with needle	25	TZGV 033 25

## **Sterility Test Media and Rinse Buffers**



Millipore sterility test culture media are manufactured in ISO 9001 manufacturing centers and have been formulated and tested to meet the requirements of the US, Japanese and European Pharmacopeias for use in sterility testing. Two types of Fluid Thioglycollate Media (FTM) are available: the USP formulation and new Clear FTM, an alternative formulation for customers who prefer a medium with extra visual clarity. The new formulation is validated to meet the performance and quality specifications set forth in the USP, EP and JP for pH, sterility, percent oxidation, and growth promotion.

#### ORDERING INFORMATION

Description	Bottle Closure	Vol. (mL)	Qty/ Pk	Catalogue No.
Soybean Casein Digest Broth (USP/EP/JP Formulation)	Screw cap with septum	100	12	STBM TSB 12
Fluid Thioglycollate (USP/EP/JP Formulation)	Screw cap with septum	100	12	STBM FTM 12
Clear Fluid Thioglycollate (USP/EP/JP Validated)	Screw cap with septum	100	12	STBM CTM 12
Fluid A (USP/EP/JP Formulation)	Screw cap with septum	100	12	STBM RFA 12
	Screw cap with septum	300	4	STBM RFA 34
Fluid D (USP/EP/JP Formulation)	Screw cap with septum	300	4	STBM RFD 34
Fluid K (USP Formulation)	Screw cap with septum	300	4	STBM RFK 34

Sterility Testing Solutions



## **Sterisure Filtration Devices**



Use Sterisure devices to test pharmaceuticals and biopharmaceuticals in an isolator. The double packaging reduces particulate transfer into the isolator or into the designated sterility testing area. The outer Sterisure package holds 10 individual packages, each containing a pair of sterilized devices. Versatile design lets you test low protein binding agents, medical devices (by direct inoculation) and diagnostic test products for the presence/absence of microorganisms. May also be used for microbial limits testing with the Milliflex PLUS pump.

Description	Qty/Pk	Catalogue No.
Sterisure filter device mixed esters of cellulose membrane 0.45 µm	10	TTHA 0F2 10
Sterisure filter device PVDF membrane 0.45 µm	10	TTHV 0F2 10
Sterisure SST filter support for manifold*	1	TA0F 000 01

# Access Services



## Standard and Custom Service Solutions from the Experts

Services are a natural extension of customer expectations that ensure that the components used in the process as well as the process itself are working at optimal performance. We provide a wide range of value-added services for instrumentation and expendables. Millipore also offers critical testing and methods development services, enabling you to better understand your process and improve risk mitigation.

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## MicroSafe Biosafety Solutions Laboratory, Europe



#### BENEFITS

- cGMP/GLP Microbiology Test Contract laboratory for biosafety compliance
- · A broad range of standard and customized mycoplasma, virus and bacteriology tests which meets regulatory requirements.
- A name you know with people you can trust - we can assemble a team of experienced scientists to design and set up the assays you need.
- State-of-the-art rapid tests for mycoplasma detection, bacterial identification and specific viral screening.

MicroSafe Biosafety Solutions Laboratory, Europe is a cGMP/GLP microbiological contract testing facility meeting the drug manufacturing testing needs of pharmaceutical and biotechnology companies.

From cell bank characterization to in-process microbiological monitoring, batch release testing and clean room monitoring and validation, we can help you ensure biosafety compliance of your drug manufacturing process.

MicroSafe Biosafety Solutions Laboratory, Europe provides validated, standard and customized testing programs for your products that meet the EP, USP, ICH, EMEA, CBER and CFR requirements and regulations.

Biosafety compliance test portfolio includes:

#### Mycoplasma Testing

- MilliPROBE Mycoplasma testing
- · QPCR Mycoplasma testing
- · Agar broth test
- · Test on indicator cells
- · Mycoplasma inactivation studies

#### Virus Testing (In vitro)

- · QPCR Rapid test for specific viruses
- · Adventitious Viruses
- Specific Adventitious Viruses (Bovine, porcine)
- · Specific Bovine viruses
- Replication Competent Retroviruses
- · Avian Leukosis virus by ELISA
- TFM
- · Virus inactivation studies

#### In Vivo Virus Assays

#### Identification/Authentication

- · DNA typing Identification for bacteria, fungi and mycoplasma species.
- · Iso Enzyme Analysis

#### **Sterility Testing**

- · Steritest EZ closed concept system in Isolator suit
- · Direct inoculation

#### **Bacterial Bioburden Testing**

- · Total viable count Membrane filtration method with Milliflex system or Pour-plate method.
- · Specified microorganisms

#### **Endotoxin Testing**

#### Other Standard Bacteriology **Testings and Studies**

- · Mycobacterium testing
- · Antibiotic potency assays
- · Growth promotion testing
- · Preservative efficacy testing
- · Environmental monitoring

For additional information, please contact your local Millipore Technical Service representative.



Access Services

## **Validation Protocols**



## Proven Protocols and Expertise to Qualify Millipore Products for Use In Your Processes

Millipore's validation protocols are based on Millipore's own internal product qualification test methods. Our extensive protocols will enable you to quickly initiate your Master Plan and perform IQ, OQ and PQ with ease.

Millipore provides complete descriptions of all the activities necessary for proving the suitability of the test methodology, calibration, and maintenance. You also get valuable information on organizing the validation effort, including the length of time it takes to complete each activity.

Validation Protocols consist of the following test methods\*.

#### Master Plan

· Defined structure, responsibilities for qualification

#### Installation Qualification (IQ)

- Verification and identification of the Millipore product
- · Verification of product's utilities and operating environment requirements
- · Equipment and personnel preparation
- SOP lists

#### **Operational Qualification (OQ)**

· Verification of product's functionality (hardware, software, devices)

#### Performance Qualification (PQ)

· Test Method suitability verification (microbiology validation procedures)

#### **ORDERING INFORMATION**

Description	Qty/Pk	Format	Catalogue No.
Steritest Equinox pump for laminar flow	1	A4	TQNX A4V P1
hoods and/or isolators validation protocol	1	US letter	TQNX LTV P1
M Air T system validation protocol	1	A4	ATAS A4V P1
	1	US letter	ATAS LTV P1
M Air T isolator validation protocol	1		ATBP 0VG 01
Milliflex PLUS pump validation protocol	1	A4	MXPP A4V P1
Milliflex PLUS pump validation protocol	1	US letter	MXPP LTV P1
Milliflex Rapid microbiology detection and	1	A4	MXRP A4V P1
enumeration system validation protocol	1	US letter	MXRP LTV P1

\* Some test methods may not be provided as standard protocols for all Millipore products. In such a case, Validation Services can be ordered on a customized basis to assist in development and implementation.

## **On-Site Validation Services**

Millipore's Validation Sciences Laboratories offers on-site validation services for laboratories that do not have the personnel and/or time commitment to perform validation on Millipore products. Millipore scientists are skilled to assist in the implementation of Millipore's Validation Protocol within your laboratory, ensuring all test criteria lead to a completely qualified and accurate test method including hardware, expendables and product testing method (S.O.P.).

## Installation Qualification, Operational Qualification, Performance Qualification Services

- · On-site support for implementation of qualification tests
- · Operator technical training
- · Execution of the test methods
- · On-site data analysis support and report generation
- · Continuous phone and email support

#### Rely on the Experts

Millipore's experienced scientists have developed qualification procedures, so you don't have to.

#### **Reduce your Validation Times**

Quickly integrate equipment into your process pipeline with confidence. Millipore's Validation Services give you the freedom and time to focus your staff on its core competencies while we perform the tests in your lab.

#### Accurate and Knowledgeable Services

With Millipore's experience in both methodologies and applicable regulations, you can quickly and successfully validate your microbial test methodologies.

#### **Reduce Costs**

Investments in resources to develop and implement hardware qualification and S.O.P validation can be reduced or eliminated with expert test methods designed by Millipore.

For addional information, please contact your local Millipore Technical Service Representative.

## Method Development

When a sterility or bioburden test method (S.O.P.) needs to be set up for a new product, or improved for a product that demonstrates antimimicrobial effects and/or filtration issues, Millipore's Validation Sciences Laboratories can develop a method that is compliant with applicable regulations (Pharmacopoeias).

#### A Name You Know

As a company, Millipore is known for the quality of its products. We apply these same high standards to our methods development assignments and keep the same strict attention to regulatory compliance.

#### People You Can Trust

Depending on the scope of your project, we can assemble a team of experienced Millipore scientists with expertise in membrane filtration, biochemistry, microbiology, pharmacology or regulatory affairs.

#### Methods You Can Validate

Whatever the assignment is, we know that the ultimate goal is validation. That's why we provide detailed, ready-to-validate methods (Standard Operating Procedure).

#### Ready When You Need Us

Can take weeks or even months to develop a new test method in-house, especially in today's busy QC or QA laboratories where time and technicians are often in short supply. Our team of experts are available around the globe to help you develop the methods you need, when you need them.

#### Ideal for Busy Contract Labs

Partnering with Millipore for QC test method development can be an excellent strategy for meeting tight deadlines. Our team of experts will quickly develop a custom test method for your client's biopharmaceutical product, thereby allowing your staff to focus on other aspects of the client's project.

#### **Developing Methods for All Kinds of Products**

- Antibiotics
- Vaccines
- · Collagen-based products
- · Emulsions
- · Human serum albumin additive
- · Blood clotting factor
- · Petrolatum-based products

#### Millipore Personnel and Facilities Dedicated to This Service:

- · Facilities: the Access laboratories are ISO certified facilities.
- Personnel and procedures: all tests are conducted by Millipore scientists in accordance with compendial guidelines.

#### **Complete Study and Accurate Report**

Method development services for Steritest and Milliflex products are performed as follows:

- · A customized test protocol will be approved by the customer.
- The method will then be developed and the following SOP parameters will be determined:
  - Required sample volume
  - Product filterability, with optimization if required
  - Choice of the appropriate filtration device/membrane
  - Choice of the appropriate pre-wetting and rinsing fluids
  - Filtration and rinsing procedure determination
- As a result you will get an optimized test method including advice for handling critical points



## **Method Development**

#### Milliflex Rapid System Services

Feasibility study:

- · Assessment of product compatibility with Milliflex Rapid ATP bioluminescence technology
- Basic test method set-up

Method development:

- · Customized test protocol
- · Assessment of product compatibility with Milliflex Rapid ATP bioluminescence technology
- Adaptation of routine SOP to Milliflex Rapid system (choice of the appropriate pre-wetting and rinsing fluids, determination of the filtration and rinsing procedure, determination of the optimal incubation time), recovery assessment with the most sensitive microorganism
- · Test method confirmation with additional microorganisms
- · Complete report with optimized test method including advice for handling critical points

#### ORDERING INFORMATION

Please contact your local Technical Service Representative to obtain a detailed and customized service quotation.

## Instrument Maintenance and Service Contracts

#### Maintenance Contracts

#### **Ensure Optimum Performance**

Proactive preventive maintenance and system verification ensures efficient operation of critical testing equipment. Every system should be serviced regularly to ensure its performance remains compliant with the specifications, as per GLP 21 CFR 58.63 (FDA) and EU GMP vol.4, 3.41. Millipore recommends checking and calibrating the systems on an annual basis. We can guarantee that your system meets our manufacturing specifications after preventive maintenance and service. Our maintenance team is also familiar with GMP/GLP procedures.

#### **Comprehensive Service Agreements**

Upon completion of the service, we will provide you with a report defining the service performed on your equipment as well as our recommendations. In addition, we will also provide you with a certificate of conformity that guarantees that the equipment meets Millipore system specifications.

#### **Annual Preventative Maintenance**

Annual preventative maintenance will reduce the risk of downtime by ensuring the equipment works within Millipore system specifications.

#### **Spare Parts**

There is no additional cost for most spare parts during the maintenance contract period. All defective wear parts will be replaced during the scheduled maintenance.



## Instrument Maintenance and Service Contracts

#### Peace of Mind

The maintenance contract is as effective as a warranty.

Emergency repairs, troubleshooting and maintenance contracts for Milliflex pumps, Milliflex Rapid system, Steritest Equinox pumps and M Air T systems are also available.

#### Loan Equipment (Premium Contracts Europe Only)

With one phone call, we will ship certified equipment to be used while your equipment is undergoing maintenance or repair. There are no additional costs for shipping equipment. Millipore will also coordinate all shipping logistics for you.

#### **One Contract for Every Situation**

- Initial contract: a full coverage contract protects your system from date of delivery. It includes system servicing and delivery of a new certificate of conformity before the end of the warranty.
- Standard and Premium contracts: full coverage contracts are available for all systems for the first 7 years (with a certified back-up system included in the Premium version)
- Standard PLUS and Premium PLUS contracts: same as Standard and Premium contracts for systems between 7 and 10 years.
- Maintenance services are also available for systems older (depending on spare parts availability).



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## Instrument Maintenance and Service Contracts

**Preventative Maintenance Contracts** 

Milliflex PLUS Pump Single Unit Kit	Catalogue No
Milliflex PLUS Single Unit Kit Initial Maintenance Contract	BSPM MP1 00
Milliflex PLUS Single Unit Kit Standard Maintenance Contract	BSPM MP1 07
Milliflex PLUS Single Unit Kit Premium Maintenance Contract*	BSPM MP1 02
Milliflex PLUS Pump Double Unit Kit	
Milliflex PLUS Double Unit Kit Initial Maintenance Contract	BSPM MP2 00
Milliflex PLUS Double Unit Kit Standard Maintenance Contract	BSPM MP2 07
Milliflex PLUS Double Unit Kit Premium Maintenance Contract*	BSPM MP2 02
Milliflex PLUS Pump Triple Unit Kit	
Milliflex PLUS Triple Unit Kit Initial Maintenance Contract at Millipore	BSPM MP3 00
Milliflex PLUS Triple Unit Kit Standard Maintenance Contract	BSPM MP3 0
Milliflex PLUS Triple Unit Kit Premium Maintenance Contract*	BSPM MP3 02
MilliSnap System	
MilliSnap Initial Maintenance Contract	BSPM MSN 0
MilliSnap Standard Maintenance Contract	BSPM MSN 0
MilliSnap Premium Maintenance Contract*	BSPM MSN 0
Steritest Equinox Pump for Laminar Flow Hoods	
Steritest Equinox LFH Initial Maintenance Contract	TSPM QNH 0
Steritest Equinox LFH Standard Maintenance Contract	TSPM QNH 0
Steritest Equinox LFH Premium Maintenance Contract*	TSPM QNH 0
Steritest Equinox Pump for Isolators	
Steritest Equinox Isolator Initial Maintenance Contract	TSPM QNS 0
Steritest Equinox Isolator Standard Maintenance Contract	TSPM QNS 0
Steritest Equinox Isolator Premium Maintenance Contract*	TSPM QNS 0
Steritest Integral Pump	
Steritest Integral Standard Maintenance Contract*	TSPM CPU 0
	TSPM CPU 02
Steritest Integral Standard PLUS Maintenance Contract*	TSPM CPU 0
Steritest Integral Premium PLUS Maintenance Contract* Steritest Integral Premium PLUS Maintenance Contract*	TSPM CPU 0 TSPM CPU 0

#### **ORDERING INFORMATION (CONTINUED)**

Steritest Compact	Catalogue No.
Steritest Compact Standard Maintenance Contract	TSPM TCP 01
Steritest Compact Premium Maintenance Contract*	TSPM TCP 02
Steritest Compact Standard PLUS Maintenance Contract*	TSPM TCP 03
Steritest Compact Premium PLUS Maintenance Contract*	TSPM TCP 04

#### Steritest Timer (Compact or Integral)

Steritest Timer Standard Maintenance Contract*	TSPM TIM 01
Steritest Timer Premium Maintenance Contract*	TSPM TIM 02
Steritest Timer Standard PLUS Maintenance Contract*	TSPM TIM 03
Steritest Timer Premium PLUS Maintenance Contract*	TSPM TIM 04

#### M Air T Sampler

M Air T Sampler Initial Maintenance Contract	ASPM ATA 00
M Air T Sampler Standard Maintenance Contract	ASPM ATA 01
M Air T Sampler Premium Maintenance Contract*	ASPM ATA 02
M Air T Sampler Standard PLUS Maintenance Contract*	ASPM ATA 03
M Air T Sampler Premium PLUS Maintenance Contract*	ASPM ATA 04

#### M Air T Isolator

M Air T Isolator Initial Maintenance Contract	ASPM ATB 00
M Air T Isolator Standard Maintenance Contract	ASPM ATB 01
M Air T Isolator Premium Maintenance Contract*	ASPM ATB 02
M Air T Isolator Standard PLUS Maintenance Contract*	ASPM ATB 03
M Air T Isolator Premium PLUS Maintenance Contract*	ASPM ATB 04

#### M Air T Compressed Gas

M Air T Comp Gas Initial Maintenance Contract	ASPM ATG 00
M Air T Comp Gas Standard Maintenance Contract	ASPM ATG 01
M Air T Comp Gas Premium Maintenance Contract*	ASPM ATG 02
M Air T Comp Gas Standard PLUS Maintenance Contract*	ASPM ATG 03
M Air T Comp Gas Premium PLUS Maintenance Contract*	ASPM ATG 04

#### Milliflex 100 Pump

Standard Maintenance Contract*	BS PM MX1 01
Milliflex 100 Premium Maintenance Contract*	BS PM MX1 02
Milliflex 100 Standard PLUS Maintenance Contract*	BS PM MX1 03
Milliflex 100 Premium PLUS Maintenance Contract*	BS PM MX1 04

Milliflex 100

#### Milliflex Sensor II Pump

Milliflex Sensor II Standard Maintenance Contract	BS PM MXS 01
Milliflex Sensor II Premium Maintenance Contract*	BS PM MXS 02
Milliflex Sensor II Standard PLUS Maintenance Contract*	BS PM MXS 03
Milliflex Sensor II Premium PLUS Maintenance Contract*	BS PM MXS 04

#### Instrument Services Without a Maintenance Contract Contact Millipore

\* Europe only.

# Membrane Filters & Plastic Funnels for Microbial Analysis



Membrane Filters & Plastic Funnels for Microbial Analysis

Microfil Filtration System	.491
Microfil V Filtration Devices	.493
Microfil S Filtration Devices	.494
EZ-Pak Membranes and Membrane Dispenser	.495
S-Pak Filters	497
Autoclave Pack (AO) and Sterile Pack (SO) Filters	.498
Hydrophobic Edge Membranes	.499
55-Plus Monitors	.500

## **Microfil Filtration System**

## Cost-effective System Uses Pre-sterilized, Ready-to-use Funnels and Membranes On a Patented Filtration Support



• No breakage

No preparation
No washing
No autoclaving
No clamps
No filter wrinkling
No by-pass

- Convenient, easy to use system for well-accepted membrane filtration method conforms to international standards: CEN, Standard Methods, WHO
- Disposable, stackable, light, recyclable plastic Microfil funnels eliminate autoclaving and minimize waste
- "Push fit" Microfil funnels seal tightlyl to manifold supports without clamps or O-rings
   assuring leak-free operation and uniform microorganism recoveries
- · Novel device lifts membrane after filtration for easy removal with forceps
- Unique Microfil support filters faster than all-glass filter apparatus
- Select manifold-mounted filtration supports for laboratory use or stand-alone on-site filtration supports
- · 100 mL or 250 mL funnels available with convenient accessory dispensers
- · Choose conventional sterile membranes or EZ-Pak membrane cartridges

#### SPECIFICATIONS

#### **Materials of Construction**

Membranes:	MCE or PVDF
Funnels:	Polypropylene
Filtration Supports and Manifolds:	Stainless steel
Funnel Graduations	20, 50 and 100 mL for 100 mL funnels 50, 100, 150, 200, 250 mL for 250 mL funnels

#### ORDERING INFORMATION

#### Equipment

Description	Catalogue No.
Microfil 3 place manifold and support	MIAC 03P 01
Microfil 1 place manifold and support	MIAC 01P 01
Microfil funnel dispenser 100 mL	MIAC FD1 01
Microfil funnel dispenser 250 mL	MIAC FD2 01
Microfil support with valve 1/4 in.	MIAC 014 01
Hand vacuum pump	MIAC HVP 01
Microfil head for Milliflex PLUS Pump	MCLH EAD 01

#### 100 mL Microfil Funnels and 47 mm Gridded MCE S-Pak Filters (150 Microfil Funnels and 150 S-Pak Filters)

Pore Size, µm	Color	Applications	Catalogue No.
0.22	white	Specific test regulations	MIGS WG1 00
0.45	black	General microbiological analysis	MIHA BG1 00
0.45	white	General microbiological analysis	MIHA WG1 00
0.7	white	Chlorinated effluents	MIHC WG1 00
0.8	black	Yeast or mold	MIAA BG1 00
0.8	white	Yeast or mold	MIAA WG1 00
1.2	white	Yeast or mold in difficult to	
		filter sample	MIRA WG1 00



## **Microfil Filtration System**

#### **ORDERING INFORMATION (CONTINUED)**

#### 100 mL Microfil Funnels and 47 mm Plain Durapore (PVDF) S-Pak Filters

(150 Microfil Funnels and 150 Membranes)

Pore Size, µm	Color	Applications	Catalogue No.
0.45	white	Broad chemical compatibility and low protein binding	MIHV WP1 00

#### 100 mL Microfil Funnels and 47 mm Gridded EZ-Pak Filters

(150 Microfil Funnels and 150 EZ-Pak Membranes)

0.22	white	Specific test regulations	MZGS WG1 01
0.45	white	General microbiological analysis	MZHA WG1 01
0.45	black	General microbiological analysis	MZHA BG1 01
0.8	white	Yeast or mold	MZAA WG1 01
0.8	black	Yeast or mold	MZAA BG1 01

## 250 mL Microfil Funnels and 47 mm Gridded MCE S-Pak Filters (150 Microfil Funnels and 150 S-Pak Membranes)

0.22	white	Specific test regulations	MIGS WG2 50
0.45	black	General microbiological analysis	MIHA BG2 50
0.45	white	General microbiological analysis	MIHA WG2 50
0.7	white	Chlorinated effluents	MIHC WG2 50
1.2	white	Yeast or mold in difficult to filter sample	MIRA WG2 50

250 mL Microfil Funnels and 47 mm Gridded EZ-Pak Filte	rs
(150 Microfil Funnels and 150 EZ-Pak Membranes)	

0.45	white	General microbiological analysis	MZHA WG2 51
0.45	black	General microbiological analysis	MZHA BG2 51
0.8	white	Yeast and mold	MZAA WG2 51

For additional information on the EZ-Pak System, please refer to page 495.

## **Microfil V Filtration Devices** Faster and Easier than Conventional Filter Holders Used for Microbiological Analysis



#### BENEFITS

- · Sterilized and ready-to-use
- · No clamps or O-rings
- Fits any standard manifold

With Microfil V filtration devices, there are no filter holders to assemble, no filter funnels to clean and no filter support sterilization is needed after each filtration. Simply snap a Microfil V filtration device off the convenient carrying tray and you're ready to test. Place the device on a standard number 8 stopper or a vacuum syringe with Luer connection. Microfil V devices are supplied fully assembled, sterilized and ready-to-use.

Funnels are attached to the filter support using our unique, patented "push-fit" seal, ensuring a perfect seal between the membrane, funnel and support without clamps or O-rings.

The Microfil V device's filter support has a curved edge, so you can easily remove the membrane after filtration while vacuum is still applied. This removes excess water that could cause growth around the rim of the filter during incubation.

#### **Consistent Recovery**

Microfil V devices ensure uniform recovery of microorganisms in three ways.

- The device's perfect "push fit" seal prevents sample by-pass
- The funnel's smooth, hydrophobic surface repels aqueous sample residues to ensure that bacteria in the sample are collected on the membrane, not on the walls of the funnel
- The convex shape of the support eliminates pleating and distortion of the membrane due to expansion, so contact between the membrane and the surface of the medium is uniform

#### SPECIFICATIONS

#### **Materials of Construction**

Membrane Filters:

	black; gridded; 0.45 μm and 0.8 μm pore size	
Funnel:	Hydrophobic; polypropylene	
Base:	Polycarbonate	
Mesh Spacer:	Polypropylene	
Funnel Graduations 20, 50, 100 mL		
Base Outlet Connection	Male Luer fitting	
Membrane Filter		
Diameter:	47 mm	
Filtration area:	9.6 cm <sup>2</sup>	

#### ORDERING INFORMATION

(Each box contains three trays of eight Microfil V filter funnels)

Description	Qty/Pk	Catalogue No.
Microfil V–100 mL; 0.45 µm MCE, white gridded	24	MVHA WG1 24
Microfil V–100 mL; 0.22 µm MCE, white gridded	24	MVGS WG1 24
Microfil V–100 mL; 0.45 µm MCE, black gridded	24	MVHA BG1 24
Microfil V–100 mL; 0.8 µm MCE, black gridded	24	MVAA BG1 24
Equipment		
Microfil V SST filter support for manifold	1	MIAC N8S 01
Silicone No. 8 perforated stopper	5	XX20 047 18
Microfil V head for Milliflex PLUS pump	1	MCCH EAD 01

#### Conforms to International Standards

The Microfil V device is designed to conform with the international standards for drinking water testing. The membrane has been certified in accordance with Standard Methods.

- Council Directive on the Quality of Water Intended for Human Consumption (98/83/EEC)
- Standard Methods for the Examination of Water and Wastewater, 21st Edition, 2005
- World Health Organization, Guidelines for Drinking Water Quality, 1997

White; gridded; 0.22 µm and 0.45 µm pore size mixed cellulose esters (MCE);

## **Microfil S Filtration Devices**

#### Ready-to-use Sterile Devices for Microbiological Testing of Pharmaceutical Water



## BENEFITS

- Sterile, individually packaged for convenience and reliability
- Protective lid reduces external contamination risk
- Pre-assembled to speed sampling and shorten preparation
- Easy-to-remove funnel and membrane reduces test time

Microfil S devices are pre-assembled and individually packaged to provide a fast and dependable alternative to conventional multi-step methods. These pre-sterilized devices combine a funnel, protective lid and filtration support so routine microbiological testing is fast and easy. No membrane handling prior to filtering. No filter holders, funnels and attachments to assemble and sterilize. No sterilizing the filter support after each filtration.

#### **Consistent Recovery**

Microfil S devices ensure uniform recovery of microorganisms in three ways.

- The funnel's smooth, hydrophobic surface repels aqueous sample residues to ensure that microorganisms are collected on the membrane, not on the walls of the funnel.
- The convex shape of the support eliminates pleating and distortion of the membrane due to expansion, so contact between the membrane and the surface of the medium is uniform.
- Three membrane selections allow versatility for your specific application.

#### **Conforms to International Standards**

The Microfil S device complies with USP/ EP guidelines. The device is supplied with a Certificate of Quality that demonstrates that the device has been quality control tested with Pharmacopeia organisms.

#### SPECIFICATIONS

#### **Materials of Construction**

Funnel:	Hydrophobic polypropylene
Base:	Polycarbonate
Membrane filters:	0.45 $\mu\text{m},$ white gridded, mixed cellulose esters (MCE)
	0.45 μm, white, non-gridded, Durapore membrane (Hydropholic polyvinylidene fluoride, PVDF)
	$0.22\ \mu\text{m},$ white gridded, mixed cellulose esters (MCE)
Mesh spacer:	Polypropylene
Lid:	Polyethylene Terephthalate (PET)
Funnel Graduations	20, 50, 100 mL
Membrane Filter	
Diameter:	47 mm
Gridding:	Ink jet grid pattern
Thickness:	115 – 180 μm
Filtration area:	9.6 cm <sup>2</sup>
Base Outlet Connection	Female Luer

#### **ORDERING INFORMATION**

	Filter Pore		
Filter Material	Size, µm	Qty/Pk	Catalogue No.
Mixed esters of cellulose	0.45	24	MVHA WGS 24
Hydrophilic PVDF	0.45	24	MVHV WPS 24
Mixed esters of cellulose	0.22	24	MVGS WGS 24
Hardware			
Microfil S SST filter support for manifold		1	MIAC N8S 01
Microfil S head for Milliflex PLUS pump		1	MCCH EAD 01

## **EZ-Pak Membranes and Membrane Dispenser**

Assured Convenience and Sterility



#### BENEFITS

- No protective papers to separate manually from membrane, saving time and eliminating contamination risk from handling membranes and packaging
- Easy-load pleated band membrane packs into dispenser

EZ-Pak membranes and dispenser are ready-to-use, sterile, individually-packed membranes with unique handling ease for easier MF method testing.

Simply press the lever to unpack and dispense one sterile membrane. The dispenser uncovers and maintains the membrane in horizontal position until operator retrieves it with forceps.

Used packaging film and paper are collected on the dispenser spool as the next membrane is dispensed, keeping work space clear throughout testing. Simply discard empty packaging bands when cartridge is used up.

Clear advantages include operating convenience, less risk of accidental membrane contamination, less care and skill required to aseptically separate membrane from packaging and reduced time per test. Special pleated band packaging facilitates loading packs of 150 membranes into the dispenser. A box contains 4 cartridges with 150 filters each or 1 cartridge with 150 filters and 150 Microfil funnels.

For accurate testing and sample processing and to assure traceability, membrane catalogue number, lot number, pore size and sequential number (from 1 to 150) are printed on the clear, protective cover of every membrane cell. Unused membranes remain safely packed in pleated band. No special precautions needed, even for extended periods between use.

Combine EZ-Pak and Microfil disposable funnel units to optimize security, speed and comfort.

#### SPECIFICATIONS

#### **Materials of Construction**

Weight	2.4 kg (5.5 lbs)
Dimensions (H × W × D)	240 mm x 160 mm x 235 mm
Membrane:	Mixed esters of cellulose membrane
Mechanical components:	Cast aluminum and Victrex <sup>®</sup> Peek <sup>™</sup> polymer
Rollers:	Ultem resin
Dispenser casing:	Stainless steel with epoxy-based paint finish and Ultem <sup>®</sup> resin

## **EZ-Pak Membranes and Membrane Dispenser**

#### ORDERING INFORMATION

#### EZ-Pak Dispenser

Description			Qty/Pk	Catalogue No.
EZ-Pak Membrane Dispens	ser		1	EZDI SP0 01
EZ-Pak Membrane: 600 (	4 bands of 150 filters)/Pk			
Pore Size, µm	Diameter, mm	Filter Color		Catalogue No.
0.45	47	white		EZHA WG4 74
0.45	47	black		MSP0 008 14
0.45	47	green		EZHA GG4 74
0.45	50	white		EZHA WG5 04
0.45	50	black		EZHA BG5 04
0.45	50	green		EZHA GG5 04
0.8	47	white		EZAA WG4 74
0.8	47	black		EZAA BG4 74
0.7	47	white		EZHC WG4 74
0.22	47	white		EZGS WG4 74

#### Sterilized Microfil Funnels and EZ-Pak Membrane (150 Microfil Funnels and 150 EZ-Pak Membranes)

Pore Size, µm	Filter Diameter, mm	Filter Color	Funnel Volume, mL	Catalogue No.
0.45	47	white	100	MZHA WG1 01
0.45	47	black	100	MZHA BG1 01
0.8	47	white	100	MZAA WG1 01
0.8	47	black	100	MZAA BG1 01
0.22	47	white	100	MZGS WG1 01
0.45	47	white	250	MZHA WG2 51
0.45	47	black	250	MZHA BG2 51

For additional information on the Microfil system, please refer to page 491.

## **S-Pak Filters** Sterile, Gridded Membrane Filters Optimized for MF Method Microbiological Analysis of Water



S-Pak sterile, individually packed, gridded membrane filters are made from mixed esters of cellulose and have been optimized for MF method microbiological analysis of water or other liquids. Full traceability is ensured by printed information on each membrane, including lot number, catalogue number and membrane type.

Type HA (0.45  $\mu$ m) for total coliform or yeast and mold analysis; type HC (0.7  $\mu$ m) for fecal coliform analysis, where the membrane's funnel-like pores enhance stressed organism recovery; type RA (1.2  $\mu$ m) yeast and mold analysis in difficult-to-filter liquids.

Certificates of quality enclosed in each box confirms Standard Methods compliance.

#### **ORDERING INFORMATION**

#### S-Pak Membrane Filters: 600 (4 boxes of 150 membranes)

#### BENEFITS

- · Sterile, individually packed filters
- Consistent performance
- · Streamlined traceability
- Range of membrane pore sizes to meet a wide variety of applications

Pore Size, µm	Filter Diameter, mm	Filter Color	Catalogue No.
0.22	47	white	GSWG 047 S6
0.45	47	black	HABG 047 S6
0.45	47	white	HAWG 047 S6
0.45	47	white no gridding	HVWP 047 S6
0.7	47	white	HCWG 047 S6
0.8	47	white	AAWG 047 S6
0.8	47	black	AABG 047 S6
1.2	47	white	RAWG 047 S6
0.8	50	black	AABG 050 S6
0.45	50	black	HABG 050 S6
0.45	50	green	HAGG 050 S6
0.45	50	white	HAWG 050 S6
1.2	50	white	RAWG 050 S6

NOTE: S-Pak membrane material is mixed esters of cellulose, except for HVWP 047 S6 (PVDF membrane).

## S-Pak Membrane Filters: 600 (4 boxes of 150 membranes) with 3 Pad Dispensers and 600 Absorbent Pads

Pore Size, µm	Filter Diameter, mm	Filter Color	Catalogue No.
0.45	47	white	HAWG 647 SP

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## Autoclave Pak (AO) and Sterile Pak (SO) Filters



Autoclave Pak (AO)

10 resealable envelopes containing 10 filters and 10 pads, requires autoclaving.

#### Sterile Pak (SO)

10 resealable envelopes containing 10 filters and 10 pads, presterilized.

#### SPECIFICATIONS

#### **Materials of Construction**

Membranes:	Mixed esters of cellulose
Pads:	Cellulose
Diameter	47 mm

#### ORDERING INFORMATION

#### AO Pak Filters, Requires Autoclaving

Color	Surface	Qty/Pk	Catalogue No.
white	plain	100	HAWP 047 A0
white	gridded	100	HAWG 047 A0
white	plain	100	GSWP 047 S0
black	gridded	100	HABG 047 S0
white	gridded	100	HAWG 047 S0
white	plain	100	HAWP 047 S0
black	gridded	100	AABG 047 S0
white	gridded	100	AAWG 047 S0
white	plain	100	AAWP 047 S0
	Color white white black white black black white white white white	ColorSurfacewhiteplainwhitegriddedwhiteplainblackgriddedwhiteplainblackgriddedwhiteplainblackgriddedwhiteplainblackgriddedwhiteplainblackgriddedwhiteplain	ColorSurfaceQty/Pkwhiteplain100whitegridded100whiteplain100blackgridded100whitegridded100whitegridded100whitegridded100whitegridded100whitegridded100whitegridded100whitegridded100whitegridded100whitegridded100

Membrane Filters & Plastic Funnels for Microbial Analysis

## **Hydrophobic Edge Membranes** Microbiological and Sterility Testing of Antibiotics and Bacteriostatic Drugs



Hydrophobic edge membranes are standard MCE filters with edges rendered hydrophobic to 3 or 6 mm widths. In antibiotic and bacteriostatic drug sterility testing by membrane filter method, the 6 mm wide non-wetting edge prevents drug intrusion under holder sealing rim.

#### APPLICATIONS

- Microbiological and sterility testing of antibiotics and bacteriostatic drugs
- · Filling machine operations
- Available in sterile or autoclave-ready packs

#### **ORDERING INFORMATION**

#### Hydrophobic Edge Membranes (47 mm with 3 mm Outer Edge, Sterile Packed)

Pore Size, µm	Color	Surface	Qty/Pk	Catalogue No.
0.22	white	plain	100	GSEP 047 S0
0.45	white	plain	100	HAEP 047 S0
0.45	white	gridded	100	HAEG 047 S0

## Hydrophobic Edge Membranes (47 mm with 3 mm Outer Edge, Autoclave Packed)

0.45	white	plain	100	HAEP 047 A0
0.45	white	gridded	100	HAEG 047 A0

## Hydrophobic Edge Membranes (47 mm with 6 mm Outer Edge, Sterile Packed).0.45whiteplain100HAEP 047 SW

## Hydrophobic Edge Membranes (47 mm with 6 mm Outer Edge, Autoclave Packed)

0.45	white	plain	100	HAEP 047 AW
0.45	white	gridded	100	HAEG 047 AW

#### Hydrophobic Edge Membranes (47 mm with 6 mm Outer Edge) Non-sterile Bulk Packed

0.22	white	plain	100	GSEP 047 0W
0.45	white	plain	100	HAEP 047 0W
3	white	plain	100	SSEP 047 0W
5	white	plain	100	SMEP 047 0W

## **55-Plus Monitor**

## A Ready-to-use and Disposable Filtration Unit for Microbiological Analysis of Beverages and In-process Water



Test beverages and other liquids faster and easier with 55-Plus monitors from Millipore. These disposable and sterilized units are a convenient and easy system that enables you to optimize the analysis time for routine testing. After sample filtration, simply add 2 mL of liquid culture media and convert the base of the unit into a Petri dish for incubation.

#### **Reduce Laboratory Workload**

These sterilized and disposable ready-to-use devices eliminate the need for washing and autoclaving of filter funnels. Preparation and handling times are greatly reduced and there is no filter assembly before testing.

#### Speed Up Sample Processing

55-Plus monitors have 50% more filtration area than conventional 47 mm filter holders and devices, resulting in faster flow rates.

#### SPECIFICATIONS

#### **Materials of Construction**

Funnel, lid and base:	Styrene
Cap:	Polyethylene
Membrane:	Mixed esters of cellulose
Absorbent pad:	Cellulose
Filter Area	21.1 cm <sup>2</sup>

#### BENEFITS

- Convenient and easy to use
- Sterilized, ready to use devices save time and expense

#### ORDERING INFORMATION

#### **55-Plus Monitors**

Description		Catalogue No.
55-Plus monitors, 50/Pk	0.45 µm, black	JBRMHBG05505
	0.45 µm, white	JBRMHWG05505
	0.8 µm, black	JBRMABG05505
55-Plus monitor connector adapter, 5/Pk		JBRM00005505

#### Growth Culture Media

2 mL liquid media ampoules, 50/Pk

For all media types, please refer to page 512.

500

# On-Line Monitoring Tools



MicropreSure On-Line Filtration Systems	502
MicropreSure Sanitary Sampling Valves	
and Adapters	504



501

## **MicropreSure On-Line Filtration Systems** Easy Method to Secure Samples for Tracking and Trending Process Water Purity



#### BENEFITS

- · Sterile and ready to use
- Eliminates risk of external contamination

The MicropreSure on-line filtration sampler improves microbiological testing of purified water at the point-of-use.

#### **Closed Design for Accurate Sampling**

The simple, protective design of the MicropreSure sampler provides dependable microbiological sampling and reduces contamination risk in any environment. Organisms are captured on the membrane right at the collection site, providing a representative sample for accurate enumeration. The filtration chamber remains closed during all stages of sampling and processing, so operator skill and environmental control are less critical.

#### Fast and Reliable In-Process Collection

The MicropreSure sampler and monitor saves steps and speeds collection – providing an easy method to secure the samples you need for tracking and trending process water purity. It uses the pressure in tanks or pressurized lines to process and collect samples through a microporous membrane within an enclosed chamber.

And because the MicropreSure devices are securely locked together, sampling pressurized water lines will not create water leaks.

#### Sampling and Filtration in One Step MicropreSure samplers and monitors are sterile and ready to use. With

sterile and ready to use. With MicropreSure on-line filtration samplers, you sample and process in one step, eliminating the need to sterilize sample containers or transport them back to the laboratory. After processing, microbes are contained and protected within the lightweight MicropreSure devices that are easily carried.

During validation, a 100 mL sample may not reveal low level microbial contaminants in a water sample. The MicropreSure sampler and monitor allows for processing liters of water through its enclosed housing. In addition, the strong fit between the Luer fitting and the sanitary sampling valve means you can continuously sample over an extended period of time. Results can then reflect contamination build-up over a batch, a shift or a day.

#### SPECIFICATIONS

#### **Materials of Construction**

Filtration Chamber/Base:	Polycarbonate	
Membrane Materials:	Mixed esters of cellulose	
Filter Support:	High density polyethylene	
Temperature Range	5 – 90 °C	
Filter Pore Size, µm	0.45	
Filtration Area, cm <sup>2</sup>	9.1	
Dimensions		
Device Height, mm:	45	
Filter Diameter, mm:	47	
Pressure Limit		
at 25 °C:	3 bar	
at 90 °C:	1 bar/1 minute/1 liter	

# On-Line Monitoring Tools



#### ORDERING INFORMATION

Samplers for Applications Requiring Membrane Transfer onto Agar Medium

Description	Qty/Pk	Catalogue No.
MicropreSure sampler, EO Sterilized, bulk packed, 0.45 µm white gridded	48	MSHA WGT 48
MicropreSure sampler, EO Sterilized, bulk packed, 0.45 µm black gridded	48	MSHA BGT 48
MicropreSure sterile sampler, individually packed, 0.45 µm white gridded	48	MSHA WGS 48
Monitors for Applications Without Membrane Transfer (liquid culture Media	only)	
MicropreSure monitors, sterilized, bulk packed, 0.45 µm white gridded	48	MSHA WGM 48
MicropreSure monitors, sterilized, bulk packed, 0.45 µm black gridded	48	MSHA BGM 48
MicropreSure monitors, sterilized, bulk packed, 0.45 µm white gridded	48	MSHA WGE 48
Accessories		
MSOpener vacuum manifold	1	MS0P ENR 01
MSOpener SST filter support for manifold	1	MS0P NMS 01
MSOpener head for Milliflex PLUS pump	1	MSPH EAD 01
Sterile sampling tube 5 in.	100	M000 000 01

For information on Valves and Valve Adapters, please refer to the next page.

## MicropreSure Sanitary Sampling Valves and Adapters

A Sampling Port for the Sterile Collection of Liquid Samples



Unique design eliminates dead spaceMid-stream sample collection

· Designed for production line sampling

These stainless steel sanitary sampling valves are idea for the sample collection of high-purity water, beverages and liquids. Easily attached to a liquid distribution line or a storage tank, the valve directs the outflow to a sampling container or a disposable filter monitor such as Millipore's MicropreSure on-line filtration sampler.

#### Sanitary Design

The valves are easily sanitized in-place using alcohol,  $\rm H_2O_2$  or steam. The valve's unique design eliminates dead spaces preventing microbial and particulate build-up, which can interfere with microbiological test results.

#### Allows Mid-stream Sample Collection

Mid-stream sample collection provides test results that accurately represent the microbial condition of the liquid in the lines or tanks.

#### Ideally Suited to the Production Line

From a stainless steel pipe or tank wall, these sample valves can process several liters of liquid through a MicropreSure on-line filtration sampler. Sample collection is accomplished in a single step within the enclosed MicropresSure chamber.

Microorganisms are contained and protected within the sterile ready-to-use MicropresSure sampler, which is hand carried to a laboratory for analysis.

#### **Quality Control**

Each sanitary sampling valve is shipped with a Certificate of Quality including a 3.1B for the stainless steel parts. For traceability and easy identification, the serial number is etched onto every valve.

#### SPECIFICATIONS

			4 4 40 5 70
	1/4 in. NP1M	1/8 in. NPTM	1 1/2 in. IC
Dimensions			
Maximum diameter:	24.0 mm	24.0 mm	50.5 mm
Length with valve closed:	90.0 mm	62.0 mm	98.0 mm
Materials of Construction			
Housing and stem:	316L stainless steel		
O-ring and plug seal:	Silicone		
Valve cap:	Polypropylene		
Connections	Male Luer-slip outlet; 1/4 in. or 1/8 in. NPTM or 1 1/2 in. TC probe connections		
Typical Flow Rate	1400 mL/min at 15 psi (1 bar)		
Maximum Operating Pressure	Up to 100 psi (7 bar) at 25 °C		
Sterilization	Steam sterilization 10 min at 135 °C; validated for up to 50 cycles at 135 °C for 10 min		
Internal Surface	Ra < 0.8 µm	Ra < 0.8 µm	Ra < 0.5 µm
Ferric Content	0.5 to 0.6%		
Indirect Food Additive	ALL component materials meet the FDA Indirect Food Additive requirements cited in 21 CFR 177 – 182.		

BENEFITS

#### ORDERING INFORMATION

Description	Qty/Pk	Catalogue No.
Sanitary Sampling Valves		
Each sampling valve includes (1) 18-gauge blunt-end syringe needle for sanitizing the unit,		
a spare O-ring, a plug seal, two ABS caps to cover the outlet Luer-slip after sanitization and user guide.		
1/4 in. NPTM, 316 stainless steel with NPT threaded connections	1	MXP ESP 14N
For use in lines with 1 1/2 in. I.D. or larger		
1/8 in. NPTM, 316 stainless steel with NPT threaded connections	1	MXP ESP 18 N
For use in lines with 3/4 in. to 1 1/2 in. I.D.		
1 1/2 in. TC, 316 stainless steel	1	MXP ESP TCL
For use in lines with 1 1/2 in. I.D. or larger		
1/4 in. weld end, 316 stainless steel. To be welded on the line.	1	MXPE SPW EL
Spare Parts and Accessories		
Silicone seal set, O-rings and plug seals	5	MXPE SP5 0R
Valve outlet caps and syringe needles	5	MXPE SP5 CN
Plastic syringe, 20 mL	12	XX11 020 12
Plastic syringe, 50 mL	5	XX11 050 05
Viton seal set, O-rings and plug seals	5	MXPE SP5 VT
EPDM seal set, O-rings and plug seals	5	MXPE SP5 EP
Related Products		
MicropreSure sampler, EO Sterilized, bulk packed, 0.45 µm white gridded	48	MSHA WGT 48
MicropreSure sterile sampler, individually packed, 0.45 µm white gridded	48	MSHA WGS 48
MicropreSure monitor with pad for liquid media, EO sterilized, bulk packed, 0.45 µm white gridded	48	MSHA WGM 48
MicropreSure sterile monitor with pad for liquid media, Individually packed, 0.45 µm white gridded	48	MSHA WGE 48
MSOpener vacuum manifold	1	MS0P ENR 01
MSOpener SST filter support for manifold	1	MS0P NMS 01
Sterile sampling tube 5 in.	100	M000 000 01



505

# Air Testing Systems





Air Testing Systems

M Air T Testing Systems	.507
M Air T Compressed Gas and Air Test Kit	. 509

### **M Air T Air Testing Systems** A Sieve-impaction Sampler With Ready-to-use Agar Cassettes



M Air T Portable Air Tester



M Air T Testers for Isolators and Compressed Gas

#### BENEFITS

- Ready-to-use cassettes, prefilled with medium, gamma-sterilized, double-sleeve packaged, certificate included
- Easy-to-use, compact, lightweight sampler, programmable, extended-life battery, delay timer to minimize risk of secondary contamination
- · USP and EP compliance certificate
- Simple colony counting through integrated grid
- Fast and reliable results with maximum recovery; large agar amount and unique micro-perforated sieve allow air sampling of up to 1 cubic meter
- Reproducible results; unit-to-unit consistency of agar surface shape
- Processes up to 1000 liters in less than 8 minutes

A lightweight air tester featuring a unique cassette design for determining the presence of viable, airborne microorganisms in critical areas. The system impacts microorganisms onto an agar surface, which is the referenced method for analyzing microbial air contamination (USP EU-GMP guidelines).

#### Air Monitoring in Isolators

The M Air T isolator system brings the convenience and performance of the M Air T concept to isolators and barrier environments. This portable system consists of a programmable pump, which remains outside the controlled area, and an independent sampling head, which uses prefilled M Air T agar cassettes.

#### **Calibration Made Easy**

Air monitoring systems must be calibrated in order to conform to Good Manufacturing Practices. You can let our service specialists calibrate your M Air T system, or you can do it yourself using the M Air T calibration kit. The kit contains everything you need: flow meter, flow rate correction table, instruction manual, calibration sieve and calibration certificate.

#### Validation and Maintenance Services

Comprehensive validation protocols and on-site validation engineers are available to make validation faster and easier. To ensure that your system's performance remains compliant with Millipore's validated specifications, Millipore offers a comprehensive range of maintenance contracts. For additional information, please refer to our Access Services section under Process Monitoring.

#### SPECIFICATIONS

Materials of Construction	
Micro-perforated sieve:	316L stainless steel
Sampling head:	Anodized aluminum
M Air T Portable Air Tester:	Epoxy-coated aluminum
M Air T Air Tester for Isolator:	304 stainless steel frame; polyurethane casing with acrylic lacquer
M Air T Portable Air Tester	
Dimensions (H x D x W):	255 mm x 105 mm x 125 mm
Weight:	1.9 kg including batteries
M Air T Air Tester for Isolator	
Dimensions (H x D x W):	200 mm x 340 mm x 325 mm
Weight:	9.3 kg
Air flow	
M Air T Air Portable Tester:	140 L/min for first 500 L; then 180 L/min for the second 500 L
M Air T Air Tester for Isolator:	136 L/min (auto-regulated)



## M Air T Air Testing Systems

#### ORDERING INFORMATION

M Air T Portable Air Tester		
Description	Qty/Pk	Catalogue No.
M Air T tester kit in carrying bag	1	ATAS 050 60
Includes: tester, battery charger, sieve with cover and accessories		
M Air T tester	1	ATAS PLR 01
M Air T battery charger 50/60 Hz	1	ATAC 050 60
M Air T tester sieve with cover	1	ATAH EAD 01
M Air T replacement batteries	1	ATAK EY0 01
Accessories (for M Air T Portable Air Tester)		
Calibration services for M Air T tester	1	MART CAL B0
M Air T calibration kit	1	ATAC AL0 01
M Air T Agar Cassettes		
(Double sleeve packaged, 6 bags with 10 cassettes each)		
M Air T cassette with TSA	60	ATSM TTD 60
M Air T cassette with TSA and beta lactamase	60	ATSM PND 60
M Air T cassette with Sabouraud Dextrose agar	60	ATSM SDD 60
M Air T empty cassette	114	ATSM C01 14
M Air T Air Tester for Isolator		
M Air T isolator kit	1	ATIS 0KI T1
Includes: Opticap XL capsule with Aervent 0.2 µm filter, pump, sampling head, tripod, tubing, clamps, connectors and gaskets		
M Air T isolator Pump	1	ATBP UMP 01
M Air T isolator Sampling head	1	ATBH EAD 01
M Air T isolator Tripod	1	ATBF EET 01
M Air T isolator Printer	1	ATBP RNT 02
M Air T isolator Tubing 3m	1	ATBT UBE 01
Opticap XL capsule with Aervent filter, 0.2 µm	3	KTGR A04 TT3
Accessories (M Air T Air Tester for Isolators)		
M Air T isolator sieve	1	ATBS EVE 01
M Air T isolator printer expendables		
(5 rolls of thermal paper; 2 ink cartridges)	1	ATBP RNT 22
M Air T Air Tester for Isolator Agar Cassettes		
(double sleeve packaged, 6 bags with 4 cassettes each)		
M Air T isolator cassette with TSA media	24	ATSM TTB 24
M Air T isolator cassette with TSA media		
(with pyruvate for VHP-sanitized environments)	24	ATSM TPB 24
Validation Protocols		
M Air T system validation protocol	1	ATAS 0VG 01
M Air T isolator validation protocol	1	ATBP 0VG 01

Millipore offers a range of services for this product including installation, validation and maintenance. For additional information, please refer to our **Access Services** section under **Process Monitoring**.



## M Air T Compressed Gas and Air Test Kit Sampling System Designed for Microbial Monitoring of Compressed Gas and Air



#### Fast Setup and Sampling, Precise Pump Control

Operators easily create and store airflow parameters, set run-time and specify criteria for multi-cycle operation on the pump's user-friendly control panel. Sampling is fast, processing 1000 L of air in fewer than 8 minutes.

A start-delay timer allows the operator to leave the area before testing begins. The system stops automatically.

#### Report Ready Data

The pump's software simplifies documentation and reporting. Operators may easily download data such as sampling parameters, operator ID, test objective and location, as well as other plant specific details to personal computers.

Validation and Maintenance Services Comprehensive validation protocols and on-site validation engineers are available to make validation faster and easier. To ensure that your system's performance remains compliant with Millipore's validated specifications, Millipore offers a comprehensive range of maintenance contracts. For additional information, please refer to our Access Services section under Process Monitoring.

## BENEFITS

- Samples compressed gasses and air for microbial contaminants
- Ensures constant air flow for consistent agar impaction and microbial recovery

#### Easy to Use, Accurate Gas and Air Sampling

The M Air T system is designed for active air sampling from isolator and barrier environments. The M Air T compressed gas and air test kit, used with the M Air T isolator pump, offers operators a uniquely convenient and reliable method of sampling compressed gas and air. The sampling head automatically converts the compressed air or gas sample, which can be at pressures of up to 5 bar (73 psi), to atmospheric conditions, thereby providing accurate, reliable sampling. Automated operation and short-duration, high-volume sampling reduces the time and effort required for monitoring and validating aseptic conditions.

#### Total Sampling Solution Minimizes Contamination Risk

Unlike other systems, which may require separate flow meters, the M Air T System is complete. There's no vacuum calibration needed and no additional equipment required that could introduce contamination into the sampling area.

#### SPECIFICATIONS

#### M Air T Compressed Gas and Air Test Kit

#### **Materials of Construction**

Pressure reducer, cone adapter, sieve and

TC clamps:	304 stainless steel
TC gaskets:	Silicone
Dimensions	
Height:	310 mm (12.2 in.)
Width:	170 mm (6.7 in.)
Depth:	130 mm (5.11 in.)
Weight:	3.5 kg (7.7 lb)
TC gaskets:	38.1 mm (1.5 in.)
TC gaskets:	101.6 mm (4 in.)

#### M Air T Air Tester for Isolator Pump

#### Materials of Construction

Frame:	304 stainless steel	
Blower:	Sheet steel, epoxy paint	
Casing:	Polyurethane with acrylic lacquer	
Handle:	Stainless steel epoxy paint	
Keypad:	Polycarbonate	
Dimensions		
Height:	200 mm (8 in.)	
Width:	325 mm (12.8 in.)	
Depth:	340 mm (13.4 in.)	
Weight:	9.3 kg (20.5 lbs)	
Power	700 W	
Sanitization	Alcohol wipe	
Air Flow	136 LPM (auto-regulated)	
Regulatory Compliance	CE marked	

## M Air T Compressed Gas and Air Test Kit

#### ORDERING INFORMATION

#### M Air T Compressed Gas/Air Kits

Description	Qty/Pk	Catalogue No.
M Air T compressed gas/air kit	1	ATBH GAS 01*
Includes: pressure reducer, cone adapter, sieve for cone adapter, clamps, gasket and silicone gasket 1-cartridge housing		
M Air T pressure reducer	1	ATBH PRE 01
M Air T cone adapter	1	ATBH CON 01
M Air T sieve for cone adapter	1	ATBC SEV 01
Clamp 1 1/2 in. TC	1	YY20 040 45
4 in. Tri-Clover clamp	1	FTPF 007 88
1 1/2 in. TC silicone gasket	10	YY20 040 55
Silicone 4 in. Tri-Clover gasket 1-cartridge housing	1	FTPF 007 89
M Air T isolator Kit	1	ATIS 0KI T1*
Includes: Opticap XL capsule with Aervent 0.2 μm filter, pump, sampling head, tripod, tubing, clamps, connectors and gaskets		
M Air T isolator pump	1	ATBP UMP 01
M Air T isolator tripod	1	ATBF EET 01
M Air T isolator sampling head	1	ATBH EAD 01
M Air T isolator printer	1	ATBP RNT 02
M Air T printer paper	1	ATBP RNT 22
M Air T isolator tubing 3 m	1	ATBT UBE 01

\* Complete M Air T Compressed Gas Device installation includes ATBHGAS01 and ATIS0KIT01.

www.millipore.com
## **Microbial Media** and Culture Dishes



Culture Media	512
Petri Dishes and Petri-Pad <sup>™</sup> Dishes	514
Pad Dispenser	514
PetriSlides™ Dish	515
Swabs and Samplers	515

### **Culture Media** Ready to Use Millipore Media



Ready-to-use Millipore media solve numerous problems in microbiology laboratories where time, equipment and trained personnel are often in short supply. Millipore media are available in convenient, single test 2 mL plastic ampoules, eliminating the manipulation of glass ampoules and avoiding the waste and spoilage associated with bulk packaged media.

Manufacturing and testing of ampouled media is conducted in strict accordance with precise quality control procedures to ensure optimal growth and maximum shelf life. Reagent grade water is used to clean glassware and make media. Other factors that affect media stability and performance, such as finished product pH, entrained gases, light exposure and temperature are carefully analyzed and controlled during the manufacturing process.

#### ORDERING INFORMATION

### Millipore Media: Standards for Reliability and Simplicity

- Nutrient media developed specifically for culturing microorganisms on membrane filters
- Selective media forms to match organism type and analytical test needs
- Precise quality control procedures during ampouled media manufacture and testing ensure optimal growth and maximum shelf life
- m-Endo medium is manufactured for use in the bacteriological analysis of potable waters in accordance with procedures referenced in Standard Methods (recent edition) and laboratory standards for equipment and materials set forth by the U.S. Environmental Protection Agency
- Dehydrated media in pads also available

#### Media in Plastic Ampoules – Unit Size 2 mL

Target Microorganisms	Product Name	Qty/Pk	Catalogue No.
Total coliform	m-Endo Total Coliform Broth	50	MHA0 00P 2E
Fecal coliform	m-FC Broth with Rosolic Acid	50	MHA0 00P 2F
Fecal coliform	m-FC Broth without Rosolic Acid	50	MHA0 0FC R2
Yeast and mold	m-Green/Schaufus Pottinger Broth	า 50	MHA0 00P 2M
Heterotrophic bacteria (stressed environment)	m-HPC Broth	50	MHA0 00P 2S
Pseudomonas species	Pseudomonas Selective Broth	50	MHA0 00P 2P
Heterotrophic and thermophilic bacteria	Tryptone Glucose Extract Broth (TGE)	50	MHA0 00P 2T
Aerobic heterotrophic microorganisms	Tryptone Glucose Extract Broth with TTC	50	MHA0 0P2 TT
Aerobic heterotrophic microorganisms	Soybean Caein Digest Broth	20	MX00 TT2 20
Yeast and mold (inhibits bacterial growth)	Yeast and Mold Selective Broth	50	MHA0 0P2 SM
Preservative resistance yeast	PRY Broth	50	MHA0 0PR Y2
Yeast and mold in fermentation products	Wallerstein broth	50	MHA0 00P 2N
Bacteria in fermentation products	Wallerstein differential Broth	50	MHA0 00P 2D
Brettanomyces species	Brettanomyces Broth	50	MHA0 0BS M2
Yeast and mold in beverage containing sodium benzoate	Morris Orange Serum Broth	50	MHA0 0MS 02
Lactic acid bacteria	MRS broth	50	MHA0 0MR S2

For additional media types, contact Millipore or visit: www.millipore.com



#### ORDERING INFORMATION (CONTINUED)

#### Culture Media

#### Dehydrated Media/Reagents in Bottles 1/Pk

Target Microorganisms	Product Name	Qty/Pk	Catalogue No.
Fecal coliform	m-FC media	110 g (1/4 lb)	MB00 000 0F
Fecal coliform	Rosolic acid	25 g	MB00 000 0R
Fecal Streptococci	KF Streptococci agar	110 g (1/4 lb)	MB00 000 0S
Total coliform	m-Endo total coliform media	110 g (1/4 lb)	MB00 000 0E
Yeast and mold	m-Green yeast and mold media	110 g (1/4 lb)	MB00 000 0Y
Heterotrophic bacteria and thermophilic bacteria	Tryptone glucose extract	110 g (1/4 lb)	MB00 000 0T
EZ-Pak membrane dispenser*		1	EZDI SP0 01

 $^{\ast}$  EZ-Pak membranes cannot be used without an EZ-Pak dispenser.



### Petri Dishes and Petri-Pad Dishes



#### Petri Dishes and Petri-Pad Dishes

#### Petri Dishes

47 mm dishes for aseptically manufactured filter cultures on broth. These dishes do not contain an absorbent pad.

#### Sterilized Petri-Pad Absorbent Pads

47 mm dishes pre-loaded with sterilized absorbent pads. Eliminates labor and cost of hand-loading pads and minimizes contamination.

#### SPECIFICATIONS

Dish: Pad:

#### Materials of Construction

Molded polystyrene	
Pure cellulose pad	

#### ORDERING INFORMATION

Description	Diameter (mm)	Qty/Pk	Catalogue No.
Petri Dish (without pad)	47	150	PD20 047 00
		600	PD20 047 05
Petri-Pad Petri Dish, Sterile (with pad)	47	150	PD20 047 S0
		600	PD20 047 S5

### **Pad Dispenser**



Rapidly dispense large numbers of pads without handling individual pads with forceps, reducing contamination risks.

Description	Qty/Pk	Catalogue No.
Canister of 100 absorbent pads	10	AP10 045 S0
1 Pad dispenser with 2 canisters of 100 absorbent pads	1	AP10 045 S1



### PetriSlides Dish for Microbiological Analysis



Substitute for Petri Dishes. Holds filter securely in place. Transparent cover allows microscopic examination without removal. Rectangular base has rounded corners for mounting on microscope stage.

#### SPECIFICATIONS

Materials of Construction	Molded polystyrene: pure cellulose pad
Dimensions	51 x 76 mm, base fits with 47 mm membrane diameter

#### ORDERING INFORMATION

Description	Qty/Pk	Catalogue No.
PetriSlides dish preloaded with absorbent pads,		
sterilized	100	PDMA 047 00
PetriSlides dish for contamination analysis, Non-sterile	100	PD15 047 00

### Swabs and Samplers Monitor Microbiological Organisms in Liquids



- Samplers use self-contained dip testers to monitor microbiological organisms in liquids
- Easy to use simply sample, incubate and count. Swab the surface and place swab back into the sterile buffer. Pour the buffer into the sampler container or a sterile membrane device, filter and incubate
- Swab Test Kits use swab and sampler combination to monitor microorganisms on equipment and other surfaces
- Just add an incubator to complete the system
- Dilution kits are available to reduce organism levels in solutions with high bacteria counts

#### SELECTION GUIDE

#### Beverage Processing

		1	
Application	Product Type	Incubation Temp °C	Incubation Time
Treated Water:	HPC sampler (total bacteria)	25 – 35	2 – 3 days
Finished Product:	HPC sampler (total bacteria)	25 – 35	2 – 3 days
	Yeast and mold sampler	28 – 32	2 – 3 days
Equipment:	HPC swab test kit (total bacteria)	25 – 35 25 – 35	2 – 3 days 2 – 3 days
Food Processing			
Raw Materials:	HPC sampler/swab test (total bacteria)	25 – 35	2 – 3 days
	Yeast and mold sampler/swab test kit	28 – 32	2 – 3 days
Finished Product:	Coli-Count sampler/swab test kit (total coliform)	35	22 – 24 hours
	HPC sampler/swab test kit (total bacteria)	25 – 35	2 – 3 days
Equipment:	HPC swab test kit (total bacteria)	25 – 35	2 – 3 days
	Yeast and mold swab test kit	28 – 32	2 – 3 days
	Coli-Count swab test kit (total coliform)	35	22 – 24 hours



### Swabs and Samplers

#### ORDERING INFORMATION

#### Samplers

Description	Color Code	Qty/Pk	Catalogue No.
Coli-Count sampler	blue	25	MC00 100 25
Yeast and mold sampler	yellow	25	MY00 100 25
Total count sampler	white	25	MT00 100 25
HPC total count sampler	red	25	MHPC 100 25
Swabs			
Swab in vial with phosphate buffer	clear	25	MMSB 100 25
Test Kits (25 samplers and 25 sv	wabs)		
Coli-count <sup>™</sup> swab test kit	blue	25 tests	MCSK 100 25
Yeast and mold swab test kit	yellow	25 tests	MYSK 100 25
Total count swab test kit	white	25 tests	MTSK 100 25
HPC total count swab test kit	red	25 tests	MSSK 100 25



## Filtration Accessories



Glass Filter Holders	.518
Hydrosol™ Stainless Steel Holder	.520
Sterifil Aseptic System and Holder	.522
Filtering Flasks	.524
Filter Holder Manifolds	.524
Vacuum/Pressure Pump	.526
Lab System 1	.527
Water Test Kits	.527
Single Chamber Incubator	.528
Dual Chamber Incubator	.529
Ultraviolet Sterilizer	.530



### **Glass Filter Holders**





Stainless steel support screen with PTFE gasket also available.

#### Applications (for 47 mm disc filters)

Use XX10 047 00 for

- Bacteriological analysis of water (using 47 mm sterile membrane filters)
- Analysis of suspended solids in water (using 47 mm depth filters)

Use XX10 047 20 for

• Bacteriological analysis applications where autoclaving filter holder with membrane in place is needed

#### Use XX10 047 30 for

- Particulate contamination analysis of oils and hydraulic fluids by gravimetric or particulate counting methods
- · Exfoliative cytology applications







#### **REPLACEMENT PARTS**

- 1 Funnel
- 2 Clamp
- 3 Base
- 4 Stopper

#### Warning:

To avoid injury, do not use glass (XX10 047 00) and stainless screen (XX10 047 30) filter holders with flammable liquids. Use holder XX10 047 20 with PTFE-faced glass base.

#### SPECIFICATIONS

#### Materials of Construction

Borosilicate glass funnel and base, anodized aluminum spring clamp, silicone stopper XX10 047 00: Coarse-frit glass filter support XX10 04720: PTFE-faced funnel and base XX10 047 30: Stainless steel screen filter support

Filter Diameter, mm: 47

Filtration Area, cm<sup>2</sup>: 9.6

Funnel Capacity, mL: 300; accessory 1 L is available

**Prefilter Diameter, mm:** 35 (thick depth prefilter) or 47 (membrane prefilter)

#### Fittings

Inlet: Funnel Outlet: No. 8 perforated stopper mounts in standard 1 L and 4 L filtering flasks

#### Dimensions

Height, cm: 22.9 Diameter, cm: 7.6

#### Diameter, cm. 7.0

Sterilization Method XX10 047 00 and XX10 047 30: UV sterilize or autoclave without filter in-place

XX10 047 20: Autoclave with filter in-place

Description	Catalogue No.
Filter Holders	
Glass filter holder with frit glass screen 47 mm	XX10 047 00
Glass filter holder PTFE-coated 47 mm	XX10 047 20
Glass filter holder with stainless steel screen 47 mm	XX10 047 30

#### REPLACEMENT PARTS

Borosilicate glass funnel 300 mL         XX10 047 04           Aluminum spring clamp 47 mm         XX10 047 03           Base for 47 mm glass/filter holder         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 08           PTFE-faced Glass Filter Holder         XX10 047 03           PTFE-faced Glass Filter Holder         XX10 047 03           PTFE-faced Glass Filter Holder         XX10 047 03           PTFE-faced glass base 47 mm         XX10 047 03           PTFE-faced glass base 47 mm         XX10 047 03           PTFE-faced funnel 300 mL         XX10 047 03           Stainless Screen Glass Filter Holder         XX10 047 04           PTFE-faced funnel 300 mL         XX10 047 03           47 mm glass base withscreen         XX10 047 03           47 mm glass base with screen         XX20 047 03           Support screen 47 mm stainless steel         XX20 047 03           PTFE faced         XX10 047 03           PTFE saket         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 03           PTE gaskt         XX10 047 03           PTFE saced funnel 300 mL         XX10 047 03           PTE gaskt         XX10 047 03           Stopper screen 47 mm stainless steel         XX20 047 03	Glass Filter Holder	
Aluminum spring clamp 47 mm         XX10 047 03           Base for 47 mm glass/filter holder         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 08           PTFE-faced Glass Filter Holder            PTFE-faced funnel 300 mL         XX10 047 03           Aluminum spring clamp 47 mm         XX10 047 03           PTFE-faced glass base 47 mm         XX10 047 03           PTE-faced glass base 47 mm         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 22           Neoprene No. 8 perforated stopper         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 03           47 mm glass base with screen         XX10 047 03           47 mm glass base with screen         XX10 047 03           Support screen 47 mm stainless steel         XX20 047 03           PTE gasket         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 04           Accessories         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 05     <	Borosilicate glass funnel 300 mL	XX10 047 04
Base for 47 mm glass/filter holder         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 08           PTFE-faced Glass Filter Holder            PTFE-faced funnel 300 mL         XX10 047 03           Aluminum spring clamp 47 mm         XX10 047 03           PTFE-faced glass base 47 mm         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 03           Stainless Screen Glass Filter Holder            PTFE-faced funnel 300 mL         XX10 047 04           Aluminum spring clamp 47 mm         XX10 047 04           41mm spring clamp 47 mm         XX10 047 03           71mm glass base with screen         XX10 047 03           47 mm glass base with screen         XX10 047 03           Support screen 47 mm stainless steel         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 05           Accessories         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 05	Aluminum spring clamp 47 mm	XX10 047 03
Neoprene No. 8 perforated stopper         XX10 047 08           PTFE-faced Glass Filter Holder         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 03           PTFE-faced glass base 47 mm         XX10 047 02           Neoprene No. 8 perforated stopper         XX10 047 02           Stainless Screen Glass Filter Holder         XX10 047 03           PTFE-faced funnel 300 mL         XX10 047 04           Aluminum spring clamp 47 mm         XX10 047 03           47 mm glass base with screen         XX10 047 03           47 mm glass base with screen         XX10 047 33           Support screen 47 mm stainless steel         XX20 047 08           PTFE gasket         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 07           Slicone tubing 3/16 in. ID 140 cm         XX10 047 07           Slicone tubing 3/16 in. ID 140 cm         XX11 047 05           High output pump 115 V/60 Hz         WP62 115 60           High output pump 115 V/60 Hz         WP62 115 60           High output pump 100 V/50 – 60 Hz         WP62 100 60	Base for 47 mm glass/filter holder	XX10 047 02
PTFE-faced Glass Filter Holder         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 03           PTE-faced glass base 47 mm         XX10 047 22           Neoprene No. 8 perforated stopper         XX10 047 03           Stainless Screen Glass Filter Holder         XX10 047 24           PTE-faced funnel 300 mL         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 03           47 mm glass base with screen         XX10 047 32           47 mm glass base with screen         XX10 047 33           Support screen 47 mm stainless steel         XX20 047 03           PTFE gasket         XX20 047 03           PTFE gasket         XX10 047 03           Accessories         XX10 047 03           Vacuum filtering flask, 1 L         XX10 047 03           Vacuum filtering flask, 4 L         XX10 047 03           Vacuum filtering flask, 4 L         XX10 047 05           V	Neoprene No. 8 perforated stopper	XX10 047 08
PTFE-faced funnel 300 mL         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 03           PTFE-faced glass base 47 mm         XX10 047 22           Neoprene No. 8 perforated stopper         XX10 047 08           Stainless Screen Glass Filter Holder         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 03           47 mm glass base with screen         XX10 047 32           47 mm glass base with screen         XX10 047 33           Support screen 47 mm stainless steel         XX20 047 08           PTFE gasket         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 44           1 L Funnel 47 mm ground glass seal         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 07           Slicone tubing 3/16 in. ID 140 cm         XX71 000 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 120 V/50 Hz         WP62 215 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	PTFE-faced Glass Filter Holder	
Aluminum spring clamp 47 mm       XX10 047 03         PTFE-faced glass base 47 mm       XX10 047 22         Neoprene No. 8 perforated stopper       XX10 047 08         Stainless Screen Glass Filter Holder       XX10 047 24         Aluminum spring clamp 47 mm       XX10 047 03         47 mm glass base with screen       XX10 047 03         47 mm glass base with screen       XX10 047 32         47 mm glass base without screen       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 08         PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 03         Neoprene No. 8 perforated stopper       XX10 047 05         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 120 V/50 Hz       WP62 220 50         High output pump 100 V/50 – 60 Hz       WP62 100 60	PTFE-faced funnel 300 mL	XX10 047 24
PTFE-faced glass base 47 mm         XX10 047 22           Neoprene No. 8 perforated stopper         XX10 047 08           Stainless Screen Glass Filter Holder         PTFE-faced funnel 300 mL           PTFE-faced funnel 300 mL         XX10 047 24           Aluminum spring clamp 47 mm         XX10 047 32           47 mm glass base with screen         XX10 047 32           47 mm glass base without screen         XX10 047 33           Support screen 47 mm stainless steel         XX20 047 08           PTFE gasket         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 026           Accessories         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 07           Silicone tubing 3/16 in. ID 140 cm         XX71 004 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 205 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	Aluminum spring clamp 47 mm	XX10 047 03
Neoprene No. 8 perforated stopperXX10 047 08Stainless Screen Glass Filter HolderXX10 047 24PTFE-faced funnel 300 mLXX10 047 24Aluminum spring clamp 47 mmXX10 047 0347 mm glass base with screenXX10 047 3247 mm glass base without screenXX10 047 33Support screen 47 mm stainless steelXX20 047 08PTFE gasketXX20 047 03Neoprene No. 8 perforated stopperXX10 047 03AccessoriesXX10 047 05Vacuum filtering flask, 1 LXX10 047 05Vacuum filtering flask, 4 LXX10 047 07Silicone tubing 3/16 in. ID 140 cmXX10 047High output pump 115 V/60 HzWP62 115 60High output pump 100 V/50 – 60 HzWP62 100 60	PTFE-faced glass base 47 mm	XX10 047 22
Stainless Screen Glass Filter Holder       XX10 047 24         PTFE-faced funnel 300 mL       XX10 047 03         Aluminum spring clamp 47 mm       XX10 047 03         47 mm glass base with screen       XX10 047 32         47 mm glass base without screen       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 08         PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 35         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 04         1 L Funnel 47 mm ground glass seal       XX10 047 04         1 L Funnel 47 mm ground glass seal       XX10 047 04         WP62 115 60       WP62 115 60         High output pump 115 V/60 Hz       WP62 205 0         High output pump 100 V/50 – 60 Hz       WP62 100 60	Neoprene No. 8 perforated stopper	XX10 047 08
PTFE-faced funnel 300 mL       XX10 047 24         Aluminum spring clamp 47 mm       XX10 047 03         47 mm glass base with screen       XX10 047 32         47 mm glass base without screen       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 08         PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 05         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 100 V/50 – 60 Hz       WP62 100 60	Stainless Screen Glass Filter Holder	
Aluminum spring clamp 47 mm       XX10 047 03         47 mm glass base with screen       XX10 047 32         47 mm glass base without screen       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 08         PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 05         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 100 V/50 – 60 Hz       WP62 100 60	PTFE-faced funnel 300 mL	XX10 047 24
47 mm glass base with screen       XX10 047 32         47 mm glass base without screen       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 08         PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 05         Accessories       XX10 047 05         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 100 V/50 – 60 Hz       WP62 100 60	Aluminum spring clamp 47 mm	XX10 047 03
47 mm glass base without screen       XX10 047 33         Support screen 47 mm stainless steel       XX20 047 08         PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 05         Accessories       XX10 047 05         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 05         Vacuum filtering flask, 5 L       XX10 047 05         Vacuum filtering flask, 6 L       XX10 047 05         Vacuum filtering flask, 7 L       XX10 047 05         Vacuum filtering flask, 9 L       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 220 V/50 Hz       WP62 220 50         High output pump 100 V/50 – 60 Hz       WP62 100 60	47 mm glass base with screen	XX10 047 32
Support screen 47 mm stainless steel         XX20 047 08           PTFE gasket         XX20 047 03           Neoprene No. 8 perforated stopper         XX10 047 08           Accessories         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 07           Silicone tubing 3/16 in. ID 140 cm         XX10 047 07           High output pump 115 V/60 Hz         WP62 115 60           High output pump 100 V/50 – 60 Hz         WP62 100 60	47 mm glass base without screen	XX10 047 33
PTFE gasket       XX20 047 03         Neoprene No. 8 perforated stopper       XX10 047 08         Accessories       XX10 047 05         Vacuum filtering flask, 1 L       XX10 047 05         Vacuum filtering flask, 4 L       XX10 047 44         1 L Funnel 47 mm ground glass seal       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 100 V/50 – 60 Hz       WP62 100 60	Support screen 47 mm stainless steel	XX20 047 08
Neoprene No. 8 perforated stopper         XX10 047 08           Accessories         XX10 047 05           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 44           1 L Funnel 47 mm ground glass seal         XX10 047 07           Silicone tubing 3/16 in. ID 140 cm         XX71 000 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	PTFE gasket	XX20 047 03
Accessories           Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 44           1 L Funnel 47 mm ground glass seal         XX10 047 07           Silicone tubing 3/16 in. ID 140 cm         XX71 000 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	Neoprene No. 8 perforated stopper	XX10 047 08
Vacuum filtering flask, 1 L         XX10 047 05           Vacuum filtering flask, 4 L         XX10 047 44           1 L Funnel 47 mm ground glass seal         XX10 047 07           Silicone tubing 3/16 in. ID 140 cm         XX71 000 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	Accessories	
Vacuum filtering flask, 4 L         XX10 047 44           1 L Funnel 47 mm ground glass seal         XX10 047 07           Silicone tubing 3/16 in. ID 140 cm         XX71 000 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	Vacuum filtering flask, 1 L	XX10 047 05
1 L Funnel 47 mm ground glass seal       XX10 047 07         Silicone tubing 3/16 in. ID 140 cm       XX71 000 04         High output pump 115 V/60 Hz       WP62 115 60         High output pump 220 V/50 Hz       WP62 220 50         High output pump 100 V/50 – 60 Hz       WP62 100 60	Vacuum filtering flask, 4 L	XX10 047 44
Silicone tubing 3/16 in. ID 140 cm         XX71 000 04           High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	1 L Funnel 47 mm ground glass seal	XX10 047 07
High output pump 115 V/60 Hz         WP62 115 60           High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	Silicone tubing 3/16 in. ID 140 cm	XX71 000 04
High output pump 220 V/50 Hz         WP62 220 50           High output pump 100 V/50 – 60 Hz         WP62 100 60	High output pump 115 V/60 Hz	WP62 115 60
High output pump 100 V/50 – 60 Hz WP62 100 60	High output pump 220 V/50 Hz	WP62 220 50
	High output pump 100 V/50 – 60 Hz	WP62 100 60



### Hydrosol Stainless Steel Filter Holder



#### **APPLICATIONS (FOR 47 MM DISC FILTERS)**

Particulate or biological contamination analysis via vacuum filtration. Includes grounding set for use with flammable liquids.

Filter holder is not autoclaveable with filter in-place.

WARNING: For filtering flammable liquids, must ground unit with included grounding screw, lead and alligator clip.

#### **Replacement Parts**

- 1 Funnel
- 2 Support Screen
- 3 Base
- 4 Gasket
- 5 Stopper



#### SPECIFICATIONS

Materials of Construction	
	Stainless steel funnel, base, and filter support screen; anodized aluminum locking ring; nylon lock-wheels; silicone stopper
Filter Diameter:	47 mm
Filtration Area:	9.6 cm <sup>2</sup>
Funnel Capacity:	650 mL
Prefilter Diameter:	35 mm (thick depth prefilter)
	47 mm (membrane prefilter)
Fittings	
Inlet:	Funnel
Outlet:	Stopper fits standard 1 L filtering flask
Dimensions	
Height:	22.9 cm
Diameter:	11.4 cm

#### ORDERING INFORMATION

Description	Catalogue No.
Hydrosol 47 mm filter holder stainless steel	XX20 047 20
Replacement Parts	
Funnel and locking ring assembly stainless steel	XX20 047 04
Support screen 47 mm stainless steel	XX20 047 08
Base for 47 mm/glass Teflon <sup>®</sup> coated filter holder	XX20 047 02
PTFE gasket	XX20 047 03
Silicone No. 8 stopper 9.5 mm (3/8 in.) hole	XX20 047 18
Replacement parts kit hydrosol holder	XX20 047 RK
Accessories	
Stainless steel funnel 100 mL	XX63 001 21
Vacuum filtering flask 1 L	XX10 047 05
Vacuum filtering flask 4 L	XX10 047 44
Silicone tubing 3/16 in. ID 140 cm	XX71 000 04
Millipore forceps stainless steel	XX62 000 06
3-place manifold PVC 47 mm	XX26 047 35
3-place manifold 47 mm stainless steel	XX25 047 35
6-place manifold 47 mm stainless steel	XX25 047 00
High output pump 115 V/60 Hz	WP62 115 60
High output pump 220 V/50 Hz	WP62 220 50
High output pump 100 V/50 – 60 Hz	WP62 100 60



### Sterifil Aseptic System and Holder



Sterifil 500

**Applications (for 47 mm Disc Filters)** Used for general filtration applications and filtration of samples for particulate or biological contamination analysis. The closed unit protects sample and filtrate from environmental contamination. The Sterifil holder and funnel are available separately (without receiver flask and cover) to use with standard 1 L vacuum filtering flask or multiple place manifold.

#### **Replacement Parts**

- 1 Sterifil funnel cover
- 2 Caps
- 3 Swinnex® filter holder
- 4 Sterifil funnel
- 5 Sterifil holder base
- 6 Support screen
- 7 O-ring
- 8 Stopper
- 9 Sterifil receiver flask
- 10 Sterifil receiver flask cover



#### SPECIFICATIONS

Materials of Construction	Polysulfone funnel, funnel cover, receiver flask and cover; polypropylene holder base, and filter support screen; silicone stopper	
Filter Diameter, mm	47	
Prefilter Diameter, mm		
	42 (thick depth prefilter)	
	47 (membrane prefilter)	
Filtration Area, cm <sup>2</sup>		
Sterifil:	13.8	
Sterifil 500:	15.2	
Funnel Capacity, mL		
Sterifil:	250	
Sterifil 500:	500	
Fittings		
Inlet:	Funnel	
Outlet:	Holder outlet stopper fits standard 1 L filtering flask	
Receiver Flask:	Receiver flask ports accept 6 mm (1/4 in.) I.D. tubing or male Luer slip connection for vacuum, drain or vent	
Cover Inlet and Vent Ports:	Female Luer slip	
Sterifil Dimensions		
Height, cm:	20.3	
Diameter, cm:	7.6	
Sterifil 500 Dimensions		
Height, cm:	14.5	
Diameter, cm:	8.5	



#### ORDERING INFORMATION

Description	Qty/Pk	Catalogue No.
Sterifil 47 mm aseptic system	1	XX11 047 00
Sterifil 250 mL funnel 47 mm	1	XX11 047 10*
Sterifil 500 mL funnel 47 mm	1	XX11 J47 50
Replacement Parts (only for XX11 047 00 and X	X11 047 10)	
Sterifil funnel cover with rubber caps	1	XX11 047 03
Gum rubber caps	100	XX11 047 11
Swinnex 13 mm filter holder polypropylene	10	SX00 013 00
Glass fiber disc with binder AP25 13 mm	100	AP25 013 00
Sterifil funnel 250 mL 47 mm polypropylene sulfone	1	XX11 047 04
Filter holder base and support screen	1	XX11 047 02
Support screen Swinnex 47 polypropylene	1	XX11 047 15
O-ring silicone (5-329) Swinnex 47	10	XX11 047 07
Silicone No. 8 stopper 9.5 mm (3/8 in.) hole	5	XX20 047 18
Sterifil receiver flask 250 mL	1	XX11 047 05
Sterifil receiver flask cover	1	XX11 047 06
Accessories		
Silicone tubing 3/16 in. ID 140 cm	1	XX71 000 04
Hand vacuum pump polypropylene	1	XKEM 001 07
3-place manifold PVC 47 mm	1	XX26 047 35
Sterifil 500 O-ring	10	XX11 J47 03
High output pump 115 V/60 Hz	1	WP62 115 60
High output pump 220 V/50 Hz	1	WP62 220 50
High output pump 100 V/50 – 60 Hz	1	WP62 100 60

 $^{\star}$  Includes components (1) to (8). Sterifil receiver flask and flask cover are excluded.

Filtration Accessories



### **Filtering Flasks**



Side arm connects to vacuum source with 3/8 in. ID hose. 1 L and 4 L flasks accept No. 8 perforated stopper. 125 mL flask accepts No. 5 stopper.

#### ORDERING INFORMATION

Description	Qty/Pk	Catalogue No.
Vacuum filtering flask, 1 L	1	XX10 047 05
Vacuum filtering flask, 4 L	1	XX10 047 44
Accessories		
Silicone tubing 3/16 in. ID 140 cm	1	XX71 000 04
Silicone No. 8 perforated stopper	5	XX20 047 18

### Filter Holder Manifolds (3-Place PVC and 3-, 6-Place Stainless Steel)



Vacuum manifolds support simultaneous filtration of three or six test samples. Use

Millipore glass, plastic or stainless steel filter holders fitted with standard No. 8 perforated stoppers over holder outlets. Manifolds connect to single vacuum

source and use separate control valves at each station for independent operation. Use vent ports on each stainless manifold station to attach Swinnex filter holders or Millex filter units to maintain sterility on test filter's downstream side.

#### SPECIFICATIONS

Materials of Construction	I
3-place, stainless steel:	Stainless steel body, 3-way valves and filter holder supports; anodized aluminum handles; stainless steel hose connector and pipe plug
6-place, stainless steel:	Stainless steel body, 3-way valves and filter holder supports; anodized aluminum handles; stainless steel hose connector and pipe plug
3-place, PVC:	PVC body; stainless steel 2-way valve; polypropylene hose adapters and handles
Fittings	
Holder:	Filter holder supports accept No. 8 silicone perforated stopper
Connectors:	(3-pl and 6-pl SS): hose adapters in 1/4 in. NPTF manifold ports for vacuum hose connection; female Luer-Lok ports, 3-way valves for vent filter attachment

#### Dimensions

			-
	3-pl SS	6-pl SS	3-pl PVC
Length, cm	45.1	87.6	45.1
Width, cm	15.2	15.2	11.4
Height, cm	15.2	15.2	11.4
Weight, kg	5.0	7.7	1.5
Sterilization Method			
3-pl and 6-pl SS:	Autoclave at 121 °C		
3-place, PVC:	Cannot be autoclaved		

**PROCESS MONITORING** 

Description	Qty/Pk	Catalogue No.
6-place manifold 47 mm stainless steel	1	XX25 047 00
3-place manifold 47 mm stainless steel	1	XX25 047 35
3-place manifold 47 mm PVC	1	XX26 047 35
Replacement Parts for Stainless Steel Manifolds		
Stainless steel filter holder support for manifold	1	XX25 047 01
3-way valve with Luer vent	1	XX25 047 02
3-way valve O-ring set	10	XX25 047 07
3-way valve O-ring clip	6	XX25 047 08
Hose adapter 1/4 in. NPTM to 3/8 in. ID	1	XX25 047 05
End bracket aluminum	1	15201
Plug 1/4 in. NPT stainless steel	2	YY13 010 09
Replacement Parts for PVC Manifold		
Filter holder support PVC	1	XX26 047 01
2-way valve 1/4 x 1/4 in.	1	XX26 047 02
1/4 in. NPTF to 5/16 in. ID hose adapter polypropylene	2	XX43 047 04
Accessories		
Millipore forceps stainless steel	1	XX62 000 06
Vacuum filtering Flask, 1 L	1	XX10 047 05
1/4 in. NPTF to 5/16 in. ID hose adapter polypropylene	2	XX43 047 04
High output pump 115 V/60 Hz	1	WP62 115 60
High output pump 220 V/50 Hz	1	WP62 220 50
High output pump 100 V/50-60 Hz	1	WP62 100 60
Alternate Filter Supports		
Milliflex SST filter support for manifold	1	MXAC 000 01
Microfil V SST filter support for manifold	1	MIAC N8S 01
Sterisure SST filter support for manifold	1	TA0F 000 01



### Vacuum/Pressure Pump



The High Output Pump features a piston-driven design for greater power. The Chemical Duty Pump has a chemically-resistant head and diaphragm for use with corrosive chemicals and solvents.

Both pumps come with 70 cm of 1/4 in. tubing and a Millex FA50 filter for in-line moisture protection. Both are UL listed and CE marked.

#### SPECIFICATIONS

(For Flow Rates Up to 37 L/min)

### High Output Pump

Maximum Vacuum, mbar (in. Hg):	921 (27.2)
Maximum Pressure, bar (psig):	5.4 (80)
Maximum Flow Rate, L/min (CFM):	34 (1.2)
Materials of Construction	
Pump, head, housing, regulator:	Cast aluminum
Dimensions	
Length, cm (in.):	25.4 (10)
Width, cm (in.):	22.9 (9)
Height, cm (in.):	20.3 (8)
Weight, kg (lbs):	5.3 (11.7)
Connections	1/4 in. stepped hose barb
Chemical Duty Pump	
Maximum Vacuum, mbar (in. Hg):	813 (24)
Maximum Pressure, bar (psig):	2.45 (35)
Maximum Flow Rate, L/min (CFM):	37 (1.3)
Materials of Construction	
Pump, head, housing, regulator:	Cast aluminum
Dimensions	
Length, cm (in.):	20.3 (8.0)
Width, cm (in.):	17.8 (7.0)
Height, cm (in.):	17.8 (7.0)
Weight, kg (lbs):	4.1 (9.0)
Connections	1/4 in. stepped hose barb

Description	Catalogue No.
High output pump 115 V/60 Hz	WP62 115 60
High output pump 220 V/50 Hz	WP62 220 50
High output pump 100 V/50 – 60 Hz	WP62 100 60
High output pump maintenance kit	WP62 MNT 00
High output pump rebuild kit	WP62 RBD 00
Chemical duty pump 115 V/60 Hz	WP61 115 60
Chemical duty pump 220 V/50 Hz	W61 220 50
Chemical duty pump 100 V/50 – 60 Hz	WP61 100 60
Chemical duty pump maintenance kit	WP61 MNT 00
Chemical duty pump rebuild kit	WP61 RBD 00

### Lab System 1



Designed for laboratories that test a few samples per day. The simple combination of a hand vacuum pump and a Sterifil system can be bench operated or used as a portable system.

#### ORDERING INFORMATION

Description	Catalogue No.
Sterifil 47 mm aseptic system	XX11 047 00
Hand vacuum pump polypropylene	XKEM 001 07

### Water Test Kits



Designed for microbiological field testing, this kit allows convenient processing of multiple samples. The kit includes a portable, battery-powered incubator, field sterilizable filter holder, hand vacuum and all the equipment to carry out microbiological assays in the field. You will need: sterile filters, Petri-Pad absorbent pads and ampouled media.

NOTE: Electrical components described on this page have not received the CE mark. All incubators are made to order. Please contact your nearest Millipore office for details on availability and delivery.

Description	Voltage	Catalogue No.
Water test kit	115 V 115 V/60 Hz	XX63 WTK 00
Water test kit	230 V 220 V/50 Hz	XX63 WTK 50

### Single Chamber Incubator



Incubate total and fecal coliforms, fecal streptococci and other microorganisms

- Complies with Standard Methods requirements
- View samples through clear plastic inner door without opening, preventing temperature fluctuations
- · Compact, lightweight, portable unit for field use

#### SPECIFICATIONS

Capacity	48 47 mm Petri Dishes	
Temperature		
Control:	30, 35, 37, 41 ± 0.5, 4.5 ± 0.2 °C	
Electrical Requirements	115 V or 230 V AC or 12 V DC rechargeable nickel-cadmium battery (included in Field Kit)	

NOTE: Electrical components described on this page have not received the CE mark. All incubators are made to order. Please contact your nearest Millipore office for details on availability and delivery.

Description	Voltage	Catalogue No.
Single chamber lab incubator	115 V/60 Hz	XX63 1K0 00
Single chamber lab incubator	230 V/50 Hz	XX63 1K0 05
Single chamber field incubator	115 V/60 Hz	XX63 1K1 15
Single chamber field incubator	230 V/50 Hz	XX63 1K2 30
Replacement Parts		
Power supply	115 V	XX63 201 15
Power supply	230 V	XX63 202 30
Nickel-cadmium battery	N/A	XX63 200 01
Battery charger	115 V	XX63 200 02
Battery charger	230 V	XX63 200 22
Small carrying bag	N/A	XX63 100 03

### **Dual Chamber Incubator**



- · Incubate total and fecal coliforms, fecal streptococci and other microorganisms
- · Complies with Standard Methods requirements
- · Separate incubation chamber temperature controls
- · Recover different organisms in single incubator
- View samples through clear plastic inner door without opening, preventing temperature fluctuations
- Portable unit for field use

#### SPECIFICATIONS

Capacity	96 (47 mm) Petri Dishes
Temperature Controls Upper Chamber:	30; 35; 37 ± 0.5; 41.5 ± 0.5; 44.5 ± 0.2 °C
Lower Chamber:	30; 35; 37 ± 0.5; 41 ± 0.5; 44.5 ± 0.2 °C
Weight	15 kg with battery charger and power supply
Electrical Requirements	Field unit includes external power supply with AC connector, rechargeable nickel cadmium battery, charger, connections for 12 V vehicle or other battery

NOTE: Lab unit includes external power supply with AC power connector only.

NOTE: Electrical components described on this page have not received the CE mark. All incubators are made to order. Please contact your nearest Millipore office for details on availability and delivery

### **Ultraviolet Sterilizer**



Rapidly decontaminate 47 mm Millipore filter holders between successive sample filtrations

- Prevents organism carry-over on funnels
- · Economical autoclaving alternative
- · Holds up to three 47 mm funnels and bases
- · Sterilizes by exposing organisms to four germicidal UV lamps

#### SPECIFICATIONS

#### Materials of Construction

Germicidal Lamps:	Sylvania No. G8T5, 2537 Angstrom
Reflectors:	Anodized aluminum
Holder Panel:	Anodized aluminum
Case:	Fiberglass
Feet:	Rubber
Dimensions	432 x 241 x 337 mm
Shipping Weight	9.8 kg (21.6 lbs)

#### ORDERING INFORMATION

Description	Voltage	Catalogue No.
UV sterilizer	115 V/60 Hz	XX63 700 00
UV sterilizer	220 V/50 Hz	XX63 700 05

#### Spare Parts

Description	Qty	Catalogue No.
UV lamp type G8T5	2	XX63 700 07



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