

User Guide

Milliflex Oasis® system using MMSYSTMM2



MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.



Table of Contents

Introduction 3	5. Performance verification	16
1. Components	6. Use of multiple pumps	17
1.1 Required items.	6.1 Material needed	.17
1.2 Description of items	6.1.1 Two pumps connected	17
1.3 Touch switch.	6.1.2 Three pumps connected	17
2. Hardware installation 5	6.2 Installation	.17
2. Hardware installation	7. Culture media growth promotion test	19
3. Testing		
3.1 Filtration units	8. Milliflex [®] cassettes	20
3.2 Media plates.		22
3.3 Testing		
3.4 Waste	10. Ordering information	23
	and the second second	24
4. Cleaning & maintenance 1:	11. Troubleshooting	24
4.1 Cleaning & maintenance table11	12. Operator & equipment safety instructions	24
4.2 Surface and internal flow sanitizers—		
compatibility tables		24
4.2.1 Surface sanitizers—compatibility tables		
4.2.2 Internal flow sanitizers—compatibility tables		
4.3 Filtration head cleaning		
4.4 Pump and filtration heads surface cleaning13		
4.5 Pump rinsing		
4.6 Filtration head autoclaving		
4.7 Pump internal flow sanitization		
4.8 Filtration head complete cleaning14	ŀ	
4.9 Filtration head gaskets and check valve replacement15	5	
4.10 Sanitization kit gaskets and valve replacement15	5	

Notice

The information in this document is subject to change without notice and should not be construed as a commitment by Merck KGaA, Darmstadt, Germany. Merck KGaA, Darmstadt, Germany assumes no responsibility for any errors that may appear in this document. This manual is believed to be complete and accurate at the time of publication. In no event shall Merck KGaA, Darmstadt, Germany be liable for incidental or consequential damages in connection with, or arising from, the use of this manual.

Introduction

The Milliflex Oasis® system is a solution for the microbial testing of aqueous fluids.

It is typically used in the **pharmaceutical industry** and provides an efficient method for monitoring in-process samples, water, aqueous raw materials and finished products for microbial limits testing.

It can also be used in the electronics industry to test bacterial levels in rinse water following deionization for microelectronics and for drinking water and beverages including beer, wine, fruit juice, soft drinks as well as their raw materials.

The Milliflex Oasis® system for microbiological examination of aqueous fluids is composed of the Milliflex Oasis® pump, the Milliflex Oasis® single-use filtration unit and the Milliflex Oasis® single-use media plate. This system provides a convenient solution for increasing the number of tests per hour while reducing the risk of false results.

Please refer to the ordering information section for details on the different items.

1. Components

1.1 Required items

Four hardware Cat. Nos. are necessary to run the system:

- 1. Milliflex Oasis® filtration pump (Cat. No. MMSYSTMM2)
- Milliflex Oasis® filtration heads (MMHEADMM2) sold separately
- 3. Milliflex Oasis® power supply for one to three filtration pumps, specific to defined regions:
 - Australia: Cat. No. MMPWRSPAU
 - Brazil: Cat. No. MMPWRSPBR
 - China: Cat. No. MMPWRSPCN
 - Denmark: Cat. No. MMPWRSPDK
 - Europe: Cat. No. MMPWRSPEU
 - Switzerland: Cat. No. MMPWRSPSZ
 - India: Cat. No. MMPWRSPIN
 - UK: Cat. No. MMPWRSPUK
 - Japan: Cat. No. MMPWRSPJP
 - USA: Cat. No. MMPWRSPUS
 - South Africa: Cat. No. MMPWRSPZA
- 4. Milliflex Oasis® internal flow sanitization kit (Cat. No. MMSANKIT1)

Optional: For higher throughput capability, it is possible to connect two or three pumps together without additional power supplies. In this case, the Milliflex Oasis® electrical cable for connecting two pumps (Cat. No. MMCABLEMM) is required for each additional pump.

Consumables: please refer to the ordering information section for details on the different items.

- 1. Filtration units
- 2. Culture media
- Consumables for the Milliflex Oasis® internal flow sanitization kit

1.2 Description of items

The Milliflex Oasis® pump package (Cat. No. MMSYSTMM2) contains

- 1. Pump body
- 2. Tubing for discarding the liquids
- 3. Accessory kit



Figure 1: Milliflex Oasis® pump (Cat. No. MMSYSTMM2) package components

Note: Milliflex Oasis® filtration heads MMHEADMM2 are not included and are sold separately.

The Milliflex Oasis® power supply package contains

- 1. Power supply
- 2. Power cable (region specific)
- 3. Two rubber fasteners

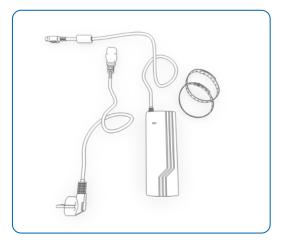


Figure 2: Milliflex Oasis® power supply package components

The Milliflex Oasis® internal flow sanitization kit (Cat. No. MMSANKIT1) package contains:

- Stainless steel sanitization kit with plug and gasket removal tool
- 2. Vacuum gauge

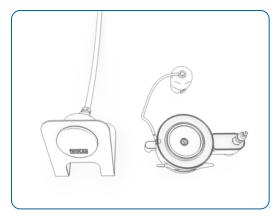


Figure 3: Milliflex Oasis® internal flow sanitization kit (MMSANKIT1) package components

The Milliflex Oasis® filtration unit package contains:

1. Three bags of eight filtration units

The Milliflex Oasis® media plate package contains:

1. Six bags of eight media plates

The Milliflex Oasis® consumable for internal flow sanitization kit (Cat. No. MMSANSYFU) package contains:

- 1. Twenty-four plastic syringes for dispensing the sanitizer
- Twenty-four funnel assemblies for rinsing with purified water

1.3 Touch switch

Meaning
Steady: pump is ready for next handling step Blinking: membrane dry out on-going
Vacuum on
The sanitization kit is ready to use
No filtration head or filtration head is not locked
Blinking: synchronizing multiple pumps, wait
No tension or standby

The switch is touch-sensitive. Use your fingertip to activate it.

Touch the center of the switch without touching the outer ring.

When the Milliflex Oasis® pump is on standby mode, it can be reactivated by touching the space between the two switches.

Note: If unused for thirty minutes, the pump switches off. Touch the switch once to power up.

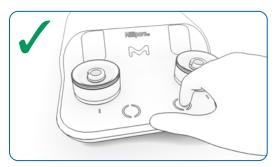


Figure 5: CORRECT finger position to start or stop the pump



Figure 4: INCORRECT—no activation if the finger touches the outer ring

2. Hardware installation

The pump must be installed on a horizontal surface. Please make sure that your working area is leveled to ensure good sample volume readings.

- Take the pump body, pump heads and tubing out of the package with care
- Take out the accessory bag and spare part bag

Optional: the accessory bag contains four stickers for customization/visual identification; select your preferred sticker and stick it carefully into the specific groove on the pump.

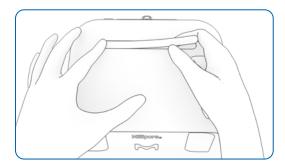


Figure 6: pump sticker set up

- Clean the exterior of the pump and the tubing using a wipe moistened with a surface sanitizer listed in the cleaning & maintenance section
- · Place the pump in the working area

When using the Milliflex Oasis® system under a horizontal laminar flow hood (LFH), the front of the pump should be placed at least at 160 mm (6.3 in.) from the front edge of the LFH (see picture).

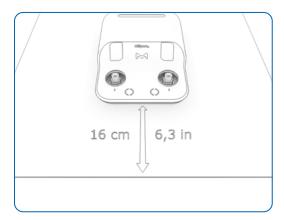


Figure 7: the front of the pump should be placed at least at 160 mm (6.3 in.) from the front edge of a horizontal LFH

 On the back of the pump, press the metal latch and remove the white plug, then connect the tubing



Figure 8: the metal latch must be pressed to remove the white plug

- Place the other end of the tubing in a liquid waste container
- Take the power supply out of its package
- Sanitize the power supply in the same way as the pump
- Plug the DC power cord to one power port situated at the back of the pump. Push the connectors into the power port until a click is heard

Important Note: DC power cord has a keyed connection, make sure you follow plugging instruction correctly.

- Connect the free power cord to the power supply
- Connect the other end of the power cord to a properly grounded power outlet

Optional: attach the power supply outside the working area with the two rubber fasteners.

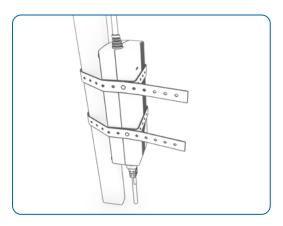


Figure 9: the power supply can be attached outside the working area with the rubber fasteners

Optional: to arrange the tubing and electrical cable in your working area, use the Milliflex Oasis® guides for electrical cable and tubing (**Cat. No. MMTUGUIDE**).

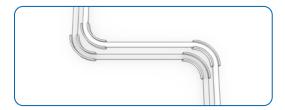


Figure 10: use of Milliflex Oasis $^\circ$ guides for electrical cable and tubing (Cat. No. MMTUGUIDE)

- Sanitize the internal flow of the pump by referring to the cleaning & maintenance section
- Once the internal flow path sanitization has been performed, take the two pump heads out of their package and remove the yellow covers

Optional: From the accessory bag, select two colored rings, clean them using a wipe and one of the sanitizers recommended in the cleaning & maintenance section, then install them on the pump heads.

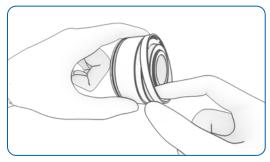


Figure 11: colored ring installation—part 1

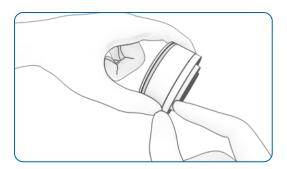


Figure 12: colored ring installation—part 2

- Clean the pump heads using a wipe moistened with a surface sanitizer listed in the cleaning & maintenance section
- Install the pump heads on the pump body
- Lock each pump head by turning clockwise until the sign on the head is aligned with the one on the pump body

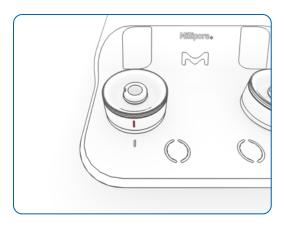


Figure 13: the sign on a locked head is aligned with the one on the pump body

The pump is ready for testing.

3. Testing

The following components are needed before starting your sample processing:

- Milliflex Oasis® pump installed following the installation section
- Milliflex Oasis® filtration units
- Milliflex Oasis® media plates
- Samples to test

Ensure that the internal pump flow was sanitized according to the cleaning & maintenance section.

 Clean the exterior of the pump using a wipe moistened with a surface sanitizer listed in the cleaning & maintenance section

3.1 Filtration units

Different types of filtration units are available (see ordering information section)

Note: for testing samples with antimicrobial activity, select filtration units with low binding Durapore membrane (Cat. No. MMHVWP124 or Cat. No. MMHVWP224).

Note: Isopropyl myristate (IPM) is not chemically compatible, therefore samples containing IPM should not be used.

• Open a box of filtration units and take out the desired number of trays or individually packed funnels.

Note for units on tray: you do not need a tool to open the box of the filtration units. Grab one end of the tape and pull it.

- Repeat the operation if more than one box of filtration units is needed.
- Clean each bag or individual package using a wipe moistened with one of the surface sanitizers listed in the cleaning & maintenance section

Optional for units on tray: if you need four filtration units or less for your testing, open the bag at the front of the safety cabinet, then pull out only half of the tray, separate the tray in two and place the "half-tray" in the working area. Fold the bag to close it and use the biggest part of the sticker situated on the bag to secure its closure. The four filtration units remaining in the bag can be put aside for later usage. In this case the bag can be opened by the sealed end, which is achieved by pulling on each side of the bag.



Figure 14: unused filtration unit storage

- Open a bag and remove the tray, then place the tray near the pump. If using individually packed units, open each package and place each filtration unit near the pump.
- Repeat the operation if more filtration units are needed Optional for units on tray: to save space, trays can be separated in two parts and stacked.



Figure 15: tray separated and stacked for space saving

Note: Four stickers with traceability information and 2D barcodes are present on each bag. It is possible to detach the stickers and stick them into a log book.

3.2 Media plates

- Open a box of media plates and remove the desired number of bags, each contains eight media plates
- Repeat the operation if more than one box of media plates is needed
- Clean each bag using a wipe moistened with one of the surface sanitizers listed in the cleaning & maintenance section
- Open the bag and place the media plates on the working area
- Repeat the operation if more media plates are needed

Note: The media plates must be at ambient temperature for optimal growth performance.

Optional: Four stickers, each with traceability information and a 2D code, are present on each bag. It is possible to detach the stickers and stick them into a log book.

3.3 Testing

When the pump is on standby mode, the switch is not lit up. To power up the Milliflex Oasis® pump, touch the front of the pump between the two switches with your fingertip.

Note: If starting a filtration without a filtration unit placed on the filtration head, you will hear a whistle noise, this is due to a check valve found in each pump head and is perfectly normal. If the pump is started after having placed a filtration unit on the pump head, this noise will not be heard.

 Place the Milliflex Oasis® filtration unit on the pump head, lining up one of the unit's frosted strips with the pump's colored background

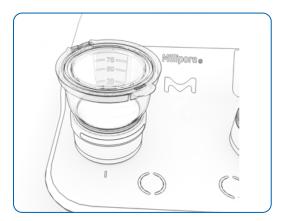


Figure 16: filtration unit placement

- · Open the filtration unit lid
- Pour the sample into the Milliflex Oasis® filtration unit and flip down the lid without locking it

Important note: When filtering a volume larger than the capacity of the filtration unit, the user should complete a proper filtration cycle including the dry out step and continue with the remaining volume(s). Alternatively, the user must ensure that the filter is always covered by 25 mL to 50 mL of liquid while filtering.



Figure 17: CORRECT lid position on the LEFT SIDE (unlocked lid)

• Touch the switch to start the filtration

Note: touch the switch three times within one second to launch the filtration on two filtration heads simultaneously.

- Open a media plate using both hands and rest the cover back on the plate
- When the liquid is totally filtered, touch the switch once more to stop the filtration, the membrane dry-out will automatically start
- When the dry-out cycle is finished, the pump stops, and the switch light stops blinking; firmly press the filtration unit lid down to lock it



Figure 18: filtration unit lid firmly pressed down with the palm to lock

 Tilt the filtration unit first, then remove it from the pump head



Figure 19: Filtration unit tilted for removal

 Optional: inspect underneath the membrane to verify that it has a convex shape



Figure 20: checking of the membrane convex shape

Note: a convex membrane shape shows that there is no leakage or pass-through (membrane and seal integrity). In addition, it helps in removing bubbles or folds between the membrane and the agar after membrane transfer.

- Open the pre-opened media plate with one hand
 Note: Be careful not to touch the agar while removing the media plate cover.
- Place the filtration unit on the media plate
- Using the thumb and index finger of each hand, push down the funnel's lid edges vertically ensuring a central contact between the membrane and the agar. Make sure the filtration unit is firmly pressed down against the media plate.

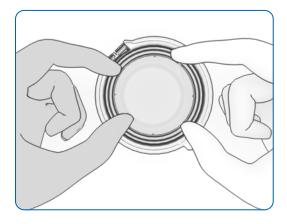


Figure 21: optimal handling for pushing down the filtration unit to the media plate

Note: pushing down the filtration unit vertically with four fingers ensures that the membrane has full contact with the agar without forming folds or bubbles.

- Open the filtration unit lid while maintaining the base with the other hand
- With the same hand, now pinch the funnel to separate it from the membrane assembly

Note: For 250 mL units, it is necessary to hold the membrane assembly (filtration unit base) with one hand while pinching the funnel with the other hand.

Tilt the lid sideways to remove it



Figure 22: CORRECT filtration unit lid removal



Figure 23: INCORRECT filtration unit lid removal

- Place the lid onto the media plate/membrane assembly and lock it
- Place the media plate upside down. It is ready for incubation

Optional: empty filtration unit trays can be used to transport and to incubate the media plates/membrane assembly. When placing media plates/membrane assemblies on the trays, the lid tab must be positioned out of the tray.

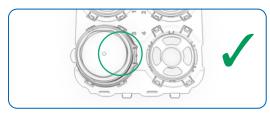
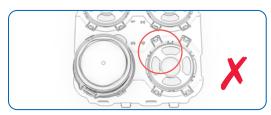


Figure 24: CORRECT media plate/membrane assembly placement (lid tab outside the tray)



 $\begin{tabular}{ll} Figure 25: INCORRECT media plate/membrane assembly placement (lid tab inside the tray) \end{tabular}$

Optional: Up to six media plates/membrane assemblies can be stacked and locked.

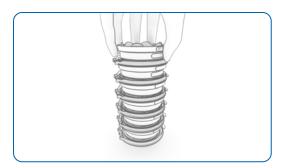


Figure 26: up to six media plates assemblies can be stacked together

 Remove the membrane support that remains on the pump by twisting it



Figure 27: membrane support removal by twisting it

Optional: it is possible to use an accessory to remove the support, the Milliflex Oasis® membrane support removal tool (Cat. No. MMSUPREMV).

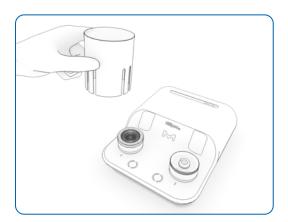


Figure 28: membrane support removal with removal tool—part 1

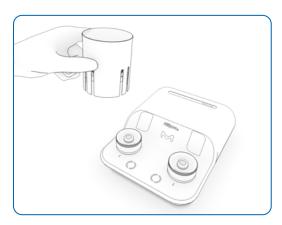


Figure 29: membrane support removal with removal tool—part 2



Figure 30: membrane support removal with removal tool—part 3

Note: If some filtered liquid remains in the pump head, it is possible to remove it with a dry, sterile wipe. Regardless of the amount of liquid, it does not impact the test results.

3.4 Waste

After use, the filtration units and membrane supports can be stacked. Place one support into a filtration unit and stack the second filtration unit, then repeat the operation to save space.



Figure 31: stacking of filtration units and membrane supports for waste

Please refer to the waste management document available on our website to recycle the filtration unit material.

4. Cleaning and maintenance

4.1 Cleaning and maintenance table

Component	Action	First installation	BEFORE each testing shift	AFTER each Workday	ONCE per Workweek	MONTHLY	YEARLY
Filtration head	Cleaning	X		X			
Pump and filtration heads	Surface cleaning	Х	Х	Х			
Pump	Internal flow sanitization	Х		Х			
Pump	Rinsing			X			
Filtration head	Complete cleaning					Х	
Filtration head	Autoclaving*	Х			X		
Filtration head	Spare parts replacement						Х
Sanitization kit	Surface cleaning			Х			
Sanitization kit	Spare parts replacement						Х

^{*} For an alternative to autoclaving, please contact your local technical support team

4.2 Surface and internal flow sanitizers—compatibility tables

Material compatibility testing was performed with the Milliflex Oasis® system using the sanitizers listed in tables 4.2.1. and 4.2.2. Sanitizer efficacy testing was not performed. Accordingly, the compatibility tables are for informational purposes only, without any representation or warranty. Seller is not responsible for compliance with any applicable biocide/antimicrobial regulations regarding any sanitizers listed herein. Customer is solely responsible for ensuring compliance with all applicable regulatory requirements, including local regulations, and generally accepted industry standards related to the use of the sanitizers, as well as obtaining any necessary intellectual property permission for use of the sanitizers.

4.2.1 Surface sanitizers—compatibility table

Surface sanitizer: Active ingredients	Dilution
Ethanol (N°CAS 64-17-5 : 226 mg/g), Chlorhexidine digluconate (N°CAS 18472-51-0 : 0.64 mg/g), Didecyldimethylammonium chloride (N°CAS 7173-51-5 : 0.53 mg/g), excipients*	Ready to use
Propan-2-ol (70%), deionized water solution (30%)*	Ready to use
Ethanol (70%)*	Ready to use
Quaternary ammonium: benzalkonium chloride (0.25–0.5%) Poly(hexamethylene biguanide) hydrochloride (0.1–0.25%)	Ready to use
Sodium hypochlorite	250 ppm
Hydrogen peroxide (6%)	Ready to use
Isopropyl alcohol (N°CAS 67-63-0 10%) Didecyldimethylammonium chloride (N°CAS 7173-51-5: 0.15936%)	Ready to use
Hydrogen peroxide (1%) and acetic acid (5.2%)	Ready to use
Peracetic acid (0.08%), hydrogen peroxide (1%), and acetic acid (<10%)	Ready to use
Quaternary ammonium: ethanol <25%, didecyldimethylammonium chloride <0.5% N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine <0.5%	Ready to use
Phenolic disinfectant: biphenyl-2-ol (CAS No 90-43-7: 7.7%) clorophene (CAS No 120-32-1: 7.7%)	8 mL/L
Alkaline disinfectant: potassium hydroxide (CAS 1310-58-3) Tetrasodium ethylenediaminetetraacetate (CAS 64-02-8)	47 mL/L

Important note: Ensure that there is no sanitizer's residuals anywhere on stainless steels parts (filtration head, filtration head support, etc). Careful rinsing with appropriate fluid shall be considered upon sanitizer agent.

st sanitizers compatible with the manometer and its support—see section 5, performance verification

4.2.2 Internal flow sanitizers—compatibility table

Internal flow sanitizers: active ingredients	Dilution
Quaternary ammonium: benzalkonium chloride (0.25–0.5%) Poly(hexamethylene biguanide) hydrochloride (0.1–0.25%)	Ready to use
Sodium hypochlorite	250 ppm
Hydrogen peroxide (6%)	Ready to use
Isopropyl alcohol (N°CAS 67-63-0 10%) Didecyldimethylammonium chloride (N°CAS 7173-51-5: 0.15936%)	Ready to use
Hydrogen peroxide (1%) and acetic acid (5.2%) **	Ready to use
Peracetic acid (0.08%), hydrogen peroxide (1%), and acetic acid (<10%) **	Ready to use

Important note: Ensure that there is no sanitizer's residuals anywhere on stainless steels parts (filtration head, filtration head support, etc). Careful rinsing with appropriate fluid shall be considered upon sanitizer agent.

The above table lists all the validated sanitizers that demonstrated a full compatibility with the Milliflex Oasis® pump. The use of other sanitizers shall be evaluated using end user's risk assessment policy, considering the pump internal materials of construction listed on section 9. System specifications, page 22 (Table: Milliflex Oasis® pump: materials in contact with the liquid filtered).

** Sanitizers compatible with the Milliflex Oasis® filtration pump MMSYSTMM2 only—the former pump generation (MMSYSTMM1) being not compatible with these 2 sanitizers.

4.3 Filtration head cleaning

 Remove the filtration heads from the pump, then remove the external gaskets.

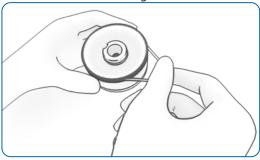


Figure 32a: External gasket removal

- Clean the external gasket's groove using a wipe moistened with a surface sanitizer listed in the cleaning & maintenance section
- Spray the upper side of the filtration head, in particular spray on the central part of the head and spray also the external gasket with the sanitizer

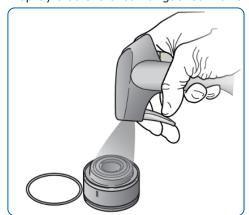


Figure 32b: Filtration head decontamination: under side

 Return the filtration head and spray the underside, in particular spray on the inner part of the head ensuring that the orange gasket and the check valve are covered with liquid

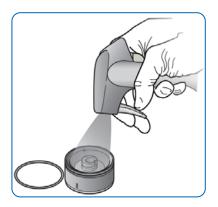


Figure 32c: Filtration head decontamination: upper side

 Wait for the sanitizer to operate for the time specified by the supplier

Note: Ensure that there is no sanitizer residuals anywhere on stainless steels parts that may lead to premature oxidation. Careful rinsing with appropriate shall be considered upon sanitizer agent.

- Put the external gasket back in place
- Clean the two filtration head supports located on the pump and remove liquid residuals if present, using a wipe moistened with the sanitizer



Figure 32d: Filtration head support decontamination

4.4 Pump and filtration heads surface cleaning

Clean the exterior of the pump, the filtration heads, the tubing, and the cable using a wipe moistened a surface sanitizer listed in the cleaning & maintenance section.

4.5 Pump rinsing

Filter 300 mL of sterile water at the end of each day. This is recommended to ensure the functionality of internal parts.

Use either a Milliflex Oasis® filtration unit or the internal flow sanitization kit with a sanitization funnel assembly to perform the rinsing.

4.6 Filtration head autoclaving

Autoclave the filtration head including its components at 121 °C for up to 30 minutes or at 134 °C for up to 15 minutes.

Pump head dimensions and weight:

Height: 31 mm (1.2 in) Diameter: 57 mm (2.2 in)

Weight: 350 g

Note: for an alternative to autoclaving, please contact your local technical support team

4.7 Pump internal flow sanitization

Important note: Sanitize the pump internal flow before using the pump the first time, after each workday, and if it remains unused for more than 7 days.

Materials:

- 1. Sanitization kit (Cat. No. MMSANKIT1)
- 2. Consumables for sanitization kit (Cat. No. MMSANSYFU)
- 3. Sanitizer (see table)
- 4. Sterile water
- · Remove the pump head
- Place a sanitization head on one pump head support and lock it
- Lock the sanitization head plug on the other support

Optional: for faster sanitization, it is possible to replace the plug by a second sanitization kit and sanitize the complete pump at once.

 Rotate the trigger counter clockwise, the switch turns green

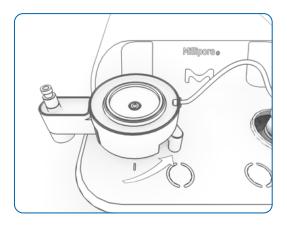
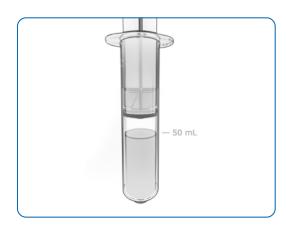


Figure 33: trigger is rotated counter clockwise

- Take one sanitization funnel assembly (sanitization kit consumable) and remove its support, then place the funnel on the kit
- Take a syringe (sanitization kit consumable) and remove its plunger
- Place and lock the syringe on the kit
- · Pour 60 mL of sanitizer in the syringe
- Introduce the plunger into the syringe

Note: An air pocket is visible over the liquid.

 Push the plunger to bring the liquid level to the 50 mL level indicator



 $\begin{tabular}{ll} \textbf{Figure 35:} & Plunger pushed to bring the liquid to the 50 mL level indication of the sanitization syringe \\ \end{tabular}$

- Open the funnel lid
- Pour sterile water up to the 250 mL indication level
- · Put back the funnel lid
- Touch the switch to start the pump

Note: the switch starts blinking for 15 minutes while the following operations occur:

- The plunger is partially pulled down and the sanitizer fills the pump internal flow path.
- 2. About 10 mL of sanitizer remains in the syringe
- 3. The sanitizer remains in contact with the internal flow for 15 minutes
- 4. The plunger is pulled down completely
- 5. The water in the funnel is pulled to rinse the pump
- 6. The switch stops blinking
- 7. The pump switches off if not in use for thirty minutes
- When the light is steady or if the pump is switched off, repeat the operation for the second flow path
- · Discard the sanitization kit consumables
- Remove the sanitization kit and clean it using a wipe moistened with one of the surface sanitizers listed in the cleaning & maintenance section

Note: Ensure that there is no sanitizer residuals anywhere on stainless steels parts that may lead to premature oxidation. Careful rinsing with appropriate shall be considered upon sanitizer agent.

We recommend the use of an alcoholic solution 70% for which residuals evaporate.

Note: the sanitization head can be autoclaved at 121 $^{\circ}$ C for up to 30 minutes or at 134 $^{\circ}$ C for up to 30 minutes.

Sanitization head dimensions and weight:

Height: 54 mm (2.1 in) width: 125 mm (4.9 in) Diameter: 70 mm (2.7 in)

Weight: 950 g

4.8 Filtration head complete cleaning

Materials:

- 1. Pump head
- 2. Gasket removal tool (to be found in the pump spare part kit or together with the sanitization kit)
- 3. Sanitizer (see table)
- Remove the filtration head from the pump
- Remove the clear external silicone gasket at the exterior of the head

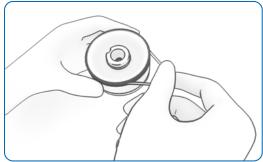


Figure 36: external gasket removal

Optional: do the same with the external colored ring (if used)

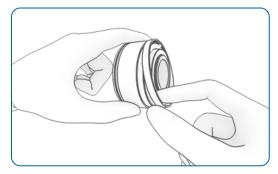


Figure 37: colored ring removal

 Remove the black check valve with the metal tool provided in the gasket kit

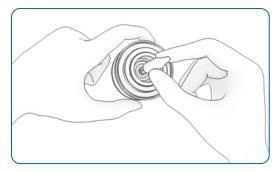


Figure 38: check valve removal with tool—part 1

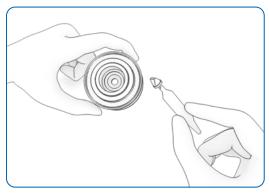


Figure 39: check valve removal with tool—part 2

- Remove the two internal gaskets using the gasket removal tool
- Clean the stainless-steel pump head carefully, including the grooves, using a wipe moistened with one of the surface sanitizers listed in the cleaning & maintenance section
- Clean the gaskets and the check valve carefully using a wipe moistened with the sanitizer
- Put the gaskets and check valve back in place using the gasket removal tool

Important note: If the check valve remains on the tool, ensure that the check valve is dry inside.

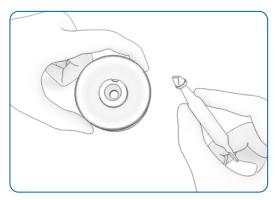


Figure 40: check valve installation with tool—part 1

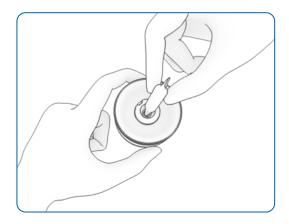


Figure 41: check valve installation with tool—part 2

4.9 Filtration head gasket and check valve (spare parts) replacement

Materials:

- 1. Pump head
- 2. Spare part kit to be found in the pump package or filtration head gasket kit **Cat. No. MMGASKTMM**

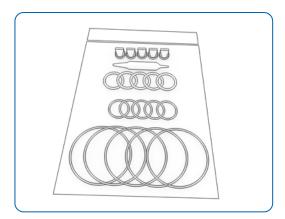


Figure 42: filtration head gasket kit (MMGASKTMM) components

- · Remove the filtration head
- Remove the gaskets and the check valve and discard them (details in previous chapter)
- Take out a set of gaskets and one (black) check valve out of the gasket kit bag and clean them using a wipe moistened with sanitizer
- Put the new gaskets and the check valve in place using the gasket removal tool (details in previous chapter)

Note: the removal tool can be autoclaved at 121 °C for up to 30 minutes or at 134 °C for up to 15 minutes.

Removal tool dimensions and weight:

Height: 70 mm (2.7 in) Diameter: 10 mm (0.4 in)

Weight: 26 g

4.10 Sanitization kit gaskets (spare parts) replacement

Materials:

- 1. Sanitization kit (Cat. No. MMSANKIT1)
- Sanitization kit gasket kit (Cat. No. MMGASKTSK) containing:
 - Five U-rings for funnel-to-kit tightness
 - Five O-rings for kit-to-pump tightness
- Remove the gaskets (using the metal tool provided with the gasket kit) from the sanitization kit and discard them
- Take out a set of gaskets out of the gasket kit bag and clean them using a wipe moistened with one of the surface sanitizers listed in the cleaning & maintenance section
- Put the new gaskets in place

5. Performance verification

The accuracy of the vacuum provided by the pump can be easily checked at any time, however this verification is not mandatory.

Materials:

- 1. Sanitization kit (Cat. No. MMSANKIT1)
- Consumables for sanitization kit (Cat. No. MMSANSYFU)
- 3. Milliflex Oasis® vacuum gauge for pump verification testing (Cat. No. MMGAUGEMM)
 - This item is provided in the sanitization kit or can be purchased separately (it comes with a certificate of calibration).
- 4. Stopwatch
- 5. Sterile water
- · Remove the pump head
- Place the sanitization kit on to the pump head support and lock it
- Lock the sanitization kit plug on the other support
- Rotate the trigger clockwise, the switch turns white
- Place sanitization funnel assembly (sanitization kit consumables) on the sanitization kit
- Connect the Milliflex Oasis® vacuum gauge to the syringe port of the kit

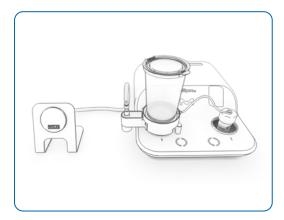


Figure 43: set up for performance verification

Internal flow prewetting step:

- Open the funnel lid, pour sterile water up to the 250 mL indication level, put back the lid on place
- 2. Touch the switch to start the filtration
- 3. Stop the filtration when it is complete
- 4. Disconnect the vacuum gauge to reset it and connect it back to the syringe port of the kit

Verification of the vacuum level and verification of the flow time:

- 5. Again, open the funnel lid, pour sterile water up to the 250 mL indication level, put back the lid on place
- 6. Start the stop watch and simultaneously start the filtration by touching the switch
- Record the vacuum level on the gauge and the time needed to complete the filtration
- 8. Stop the filtration when there is no more water
- Disconnect the vacuum gauge to reset it and connect it back to the syringe port of the kit
- 10. Repeat steps 4 to 9 twice more

Check that the average values are within the following specifications.

Pressure	Filtration time
≤-0.4 bars	≤25 seconds for 250 mL water

 Remove the sanitization kit and clean it using a wipe moistened with a surface sanitizer listed in the cleaning & maintenance section

Note: use only the top three sanitizers listed in the section 4.2.1 to clean the manometer and its support

6. Use of multiple pumps

Up to three pumps can be connected providing the following benefits:

- Higher throughput
- · Use of single power supply
- Daisy chain start: up to six samples filtered with a single push of a button

6.1 Material needed

6.1.1 Two pumps connected:

- Two Milliflex Oasis® pumps (Cat. No. MMSYSTMM2)
 Filtration heads to be ordered separately (MMHEADMM2)
- Milliflex Oasis® electrical cable for connecting two pumps (Cat. No. MMCABLEMM)
- Milliflex Oasis® power supply, the Cat. No. is specific to defined regions:

- Australia: Cat. No. MMPWRSPAU

- Brazil: Cat. No. MMPWRSPBR

- China: Cat. No. MMPWRSPCN

- Denmark: Cat. No. MMPWRSPDK

- Europe: Cat. No. MMPWRSPEU

- Switzerland: Cat. No. MMPWRSPSZ

- India: Cat. No. MMPWRSPIN

- UK: Cat. No. MMPWRSPUK

- Japan: Cat. No. MMPWRSPJP

- USA: Cat. No. MMPWRSPUS

- South Africa: Cat. No. MMPWRSPZA

Optional: Milliflex Oasis® T connectors for tubing (Cat. No. MMTCNNECT)

6.1.2 Three pumps connected:

- Three Milliflex Oasis® pumps (Cat. No. MMSYSTMM2) - Filtration heads to be ordered separately (MMHEADMM2)
- Two Milliflex Oasis® electrical cables for connecting two pumps (Cat. No. MMCABLEMM)
- Milliflex Oasis® power supply, the Cat. No. is specific to defined regions

Optional: Milliflex Oasis® T connectors for tubing (Cat. No. MMTCNNECT)

6.2 Installation

The pumps must be installed on a level surface to ensure good sample volume readings.

- Take the pump bodies and the tubing out of the package with care
- Take out the accessory bags

Optional: the accessory bag contains four stickers, select your preferred sticker and stick it carefully to the specific groove on each pump.

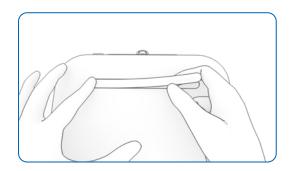


Figure 44: pump sticker set up

- Clean the exterior of the pumps and the tubing using a wipe moistened with with one of the surface sanitizers listed in the cleaning & maintenance section
- Place the pumps in the working area

When using the Milliflex Oasis® system under a horizontal laminar flow hood (LFH), the front of the pumps must be placed at least at 160 mm (6.3 in.) from the front edge of the LFH (see picture).

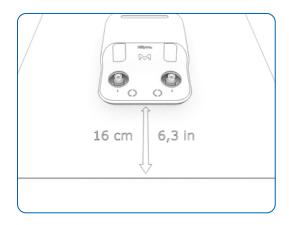


Figure 45: the front of the pump must be placed at least at 160 mm (6.3 in.) from the front edge of a horizontal LFH

- At the back of each pump, press the metal latch and remove the white plug, then connect the tubing
- Place the other end of the tubing into a liquid waste container

Optional: to save space, it is possible to connect the tubing together using the Milliflex Oasis® T connectors (**Cat. No. MMTCNNECT**). In this case cut the tubing to the desired length and connect them.

- Take the power supply out of its package
- Clean the power supply as described previously
- Use the Milliflex Oasis® electrical cable for connecting two pumps (Cat. No. MMCABLEMM) to connect one power port of pump A to one power port of pump B. Repeat for the third pump if applicable
- Push the connectors into the power ports until a click is heard
- Plug the DC power cord in the free power port, at the back of the Milliflex Oasis® pump A
- Connect the free power cord to the power supply
- Connect the other end of the power supply to a properly grounded power outlet

Optional: to arrange the tubing and the electrical cable in your working area, it is possible to use the Milliflex Oasis® guides for electrical cable and tubing (**Cat. No. MMTUGUIDE**).

Optional: attach the power supply outside the working area with the two rubber fasteners.

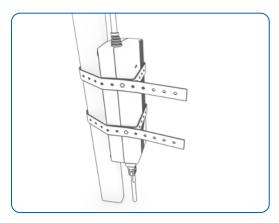


Figure 46: the power supply can be attached outside the working area with the rubber fasteners

 For each pump, remove the two pump heads from their package and remove the yellow covers

Optional: From the accessory bags, select colored rings, clean them using a wipe and one of the sanitizers recommended in the cleaning & maintenance section, then install them on the pump heads.

- Clean the pump heads using a wipe moistened with a surface sanitizer listed in the cleaning & maintenance section
- Install the pump heads on the pump bodies
- Lock the pump heads by turning clockwise until the sign on the head is aligned with the one on the pump body



Figure 47: the sign on a locked head is aligned with the one on the pump body

• Sanitize the internal flow path of the pumps, please refer to the sanitization procedure described in the cleaning & maintenance section

The pumps are ready for testing.

To start multiple filtrations simultaneously (daisy chain), touch the switch three times within one second. Please refer to the testing section of this manual for the other steps of the testing.

7. Culture media growth promotion test

The culture media growth promotion test, as described in the fully harmonized pharmacopoeias (USP <61>, EP 2.6.12, JP 4.05 part 1), can be performed using the growth promotion accessory (Cat. No. MMRECVERY), which is a Milliflex Oasis® funnel without membrane.

This accessory allows for good inoculum spreading and includes a lid to close the media plate.

This section describes the use of this accessory:

- Obtain and prepare the appropriate microbiological cultures according to internal SOPs or pharmacopeia guidelines. Concentrations should be less than or equal to 100 Colony Forming Units (CFU) per sample
- Place the media plates in the working area
- Place a tray of Milliflex Oasis® funnels without membranes (Cat. No. MMRECVERY) in the working area
- · Remove the media plate cover
- · Remove the funnel assembly support
- Place the funnel assembly on the media plate
- Make sure the funnel assembly is firmly pressed down against the media plate

- Remove the funnel by pinching it while maintaining the base with the other hand
- Tilt the funnel lid sideways to remove it and store it under the workspace. Discard the unused funnel
- Dispense the inoculum sample onto the surface of the media plate assembly and use a sterile spreader to spread the inoculum on the medium

Note: it is recommended to spread no more than 50 μ L on a media plate assembly. For method consistency, the same volume must be spread on the control Petri plate.

- Cover the spiked media plate assembly with the funnel lid
- Incubate the media plate assembly at the specified temperature and time

Note: Incubate the media plate assembly with the lid facing down.

8. Milliflex® cassettes

These products (older generation) can be used instead of Milliflex Oasis® media plates. These products do NOT have the following features:

- · Traceability stickers
- Traceability labels
- · Color coding
- · Stacking and locking features

Prefilled Milliflex® cassettes

Description:

Milliflex® Cassette Sabouraud Dextrose Agar (w/Chloramphenicol)

Milliflex® Cassette m-Endo Agar for the detection of coliforms

Milliflex® Cassette PCA Agar for the detection of bacteria in water

 $\operatorname{Milliflex}^{\mathbb{B}}$ Cassette Cetrimide Agar with Naladixic Acid for detection of P. aeruginosa

Milliflex® Cassette TSA and lecithin agar for the detection of heterotrophic microorganisms

Milliflex® Cassette HPC agar media, for detection of stressed heterotrophic plate count bacteria

Milliflex® Cassette KF Strep Agar for the detection of fecal streptococci

 $Milliflex^{\circ}$ Cassette PIA Agar for the detection and recovery of P. aeruginosa

 ${\sf Milliflex}^{\sf @}$ Cassette MacConkey agar for detection of lactose fermenting bacteria and coliforms

Milliflex® empty cassettes

Empty cassettes are available for those users who would like to prepare their own culture media.

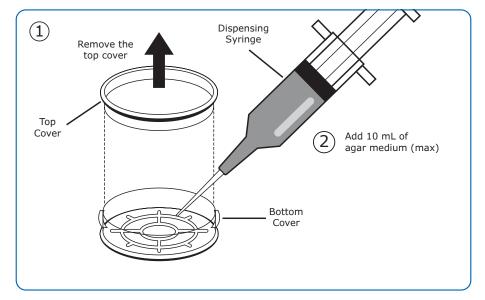
Milliflex® empty cassette for agar media (Cat. No. MXSMC0120)

- Prepare the agar medium for dispensing, and have a suitable refilling dispense syringe or pipette ready.
 Liquefy the solid agar medium and maintain at less than 60 °C.
- Remove the frosted top cover of the cassette. (1)
- Use a dispensing syringe or pipette to add 9.5–10 mL of agar into the center of the cassette.

Note: Do not add more than 10 mL of agar to the cassette to avoid spilling media into the internal gutter.

 Rest the cover back over the cassette, without pushing it into place, and allow the agar to solidify.
 Replace the cover by pushing it into place. (3)

Note: Do not close the cassette until the agar solidifies.



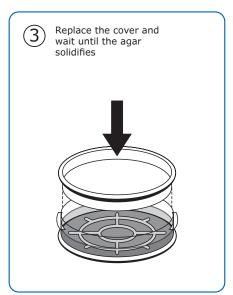


Figure 48: steps to prepare a solid medium cassette

Milliflex® empty cassette for liquid media (Cat. No. MXLMC0120)

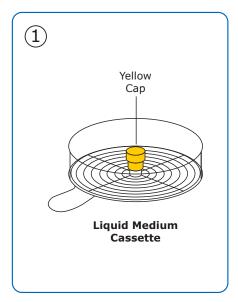
Use the following steps to prepare a liquid medium cassette:

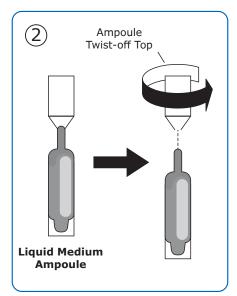
- ullet Remove the yellow cap from the cassette $oldsymbol{1}$
- Open the ampoule of medium by twisting off the ampoule top. (2)
- Insert the male Luer tip of the ampoule into the female Luer opening of the cassette.

• Squeeze the ampoule to dispense the medium into the cassette. Use the entire content of the ampule. (3)

Note: Avoid pressing the cassette on the working surface while inserting the media, since this might compress the pad and slow the introduction of the media.

 Remove the empty ampoule and firmly attach the yellow cap. The protective Tyvek® paper cover remains on the cassette. Remove it before using the cassette.





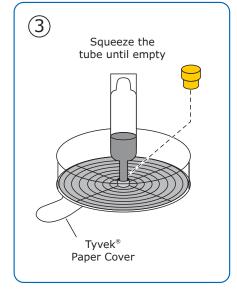


Figure 49: steps to prepare a liquid media cassette

9. System specifications

Milliflex Oasis®	Milliflex Oasis® pump		
Frame	Acrylonitrile Styrene Acrylate and Polycarbonate, compatible with standard UV sterilization		
Filtration	Two per pump, Stainless steel, silicone, rubber gaskets		
heads	Note: The pump head including all its components can be autoclaved at 121 °C for up to 30 minutes OR at 134 °C for up to 15 minutes.		
Pump dimension	Pump dimensions		
Height	90 mm (3.5 in.)		
Width	230 mm (9.0 in.)		
Depth	310 mm (12.2 in.)		
Filtration support height	70 mm (2.8 in.)		

100 V-240 VAC - 50/60 Hz - 2.5 A — One set can be used for up to three pumps

3.4 kg (7.5 lb)

24 VDC - 6.25

Weight with filtration heads

Power supply input

Power supply outcome

Milliflex Oasis® funnels	
Filtration unit	
Funnel, support & lid material	Styrene butadiene copolymer (SBC)
Membrane ring material	Polyethylene (PE)
Height 100 mL funnel	57 mm (2.2 in.)
Height 250 mL funnel	113 mm (5.5 in.)
Maximal diameter	82 mm (3.2 in.)
2D code identification	Datamatrix, can be read with standard 2D reader
Sterilization	E-beam irradiation
Membrane	
Material	Mixed Cellulose Esters (MCE) or low binding PVDF Durapore
Color	White or black
Pore size	0.45 μm or 0.22 μm
Diameter	49 mm (1.9 in.)

Milliflex Oasis® media plates		
Material	Polystyrene (PS)	
R2A plate color	Blue	
TSA plate color	Green	
SDA plate color	Pink	
Maximal diameter	66 mm (2.6 in.)	
2D code identification	Datamatrix, can be read with standard 2D reader	

Milliflex Oasis® pump: materials in contact with the liquid filtered		
Part	Material	
Filtration head	Stainless steel AISI 316 L Silicone (gaskets & check valve)	
Inner tubing	Low-density polyethylene (LDPE)	
Tubing fittings	Polyphenylsulfone (PPSU) Polypropylene (PP) Acetal Buna N rubber	
Core pump module	Polypropylene (PP) FFKM (perfluoroelastomer) PTFE (Teflon®)	
Drain tubing	Silicone	

10. Ordering information

Description	Qty/pack	Cat. No.
Filtration units		
Milliflex Oasis® 100 mL funnel, 0.45 μm white gridded, mixed cellulose esters (MCE) membrane	24	MMHAWG124
Milliflex Oasis® 250 mL funnel, 0.45 μm white gridded, mixed cellulose esters (MCE) membrane	24	MMHAWG224
Milliflex Oasis® 100 mL funnel, 0.45 μm black gridded, mixed cellulose esters (MCE) membrane	24	MMHABG124
Milliflex Oasis® 100 mL funnel, 0.22 μm white gridded, mixed cellulose esters (MCE) membrane	24	MMGSWG124
Milliflex Oasis® 100 mL funnel, 0.45 μm white plain, PVDF Durapore® membrane	24	MMHVWP124
Milliflex Oasis® 250 mL funnel, 0.45 μm white plain, PVDF Durapore® membrane	24	MMHVWP224
Milliflex Oasis® rapid 100 mL funnel, 0.45 μm white plain, PVDF Durapore® membrane	24	MMHVMFX24
Milliflex Oasis® funnel without membrane, growth promotion accessory	24	MMRECVERY
Culture media		
Milliflex Oasis® R2A low nutrient media plates	48	MMSMCRA48
Milliflex Oasis® Tryptic Soy media plates for detection of aerobic and anaerobic flora	48	MMSMCTS48
Milliflex Oasis® Sabouraud Dextrose media plates for detection of Yeast & Molds	48	MMSMCSD48
Milliflex® cassette Sabouraud Dextrose Agar (w/Chloramphenicol)	48	MXSMCSP48
Milliflex® cassette m-Endo Agar for the detection of coliforms	48	MXSMEND48
Milliflex® cassette PCA Agar for the detection of bacteria in water	48	MXSMPCA48
Milliflex® cassette Cetrimide Agar with Naladixic Acid for detection of <i>P. aeruginosa</i>	48	MXSMCET48
Milliflex® cassette TSA and lecithin agar for the detection of heterotrophic microorganisms	48	MXSMTLP48
Milliflex® cassette HPC agar media, for detection of stressed heterotrophic plate count bacteria	48	MXSMHPC48
Milliflex® cassette KF Strep Agar for the detection of fecal streptococci	48	MXSMKFS48
Milliflex® cassette PIA Agar for the detection and recovery of <i>P. aeruginosa</i>	48	MXSMPIA48
Mac Conkey Milliflex® agar for detection of lactose fermenting bacteria and coliforms	24	MXSMCMC24
Milliflex® empty cassette for agar media	120	MXSMC0120
Milliflex® empty cassette for liquid media	120	MXLMC0120
Hardware, accessories, spare parts and services		
Milliflex Oasis® filtration pump, body pump only—no filtration heads and no power supply	1	MMSYSTMM2
Milliflex Oasis® power supply for one to three filtration pumps—Australia	1	MMPWRSPAU
Milliflex Oasis® power supply for one to three filtration pumps—Brazil	1	MMPWRSPBR
Milliflex Oasis® power supply for one to three filtration pumps—China	1	MMPWRSPCN
Milliflex Oasis® power supply for one to three filtration pumps—Denmark	1	MMPWRSPDK
Milliflex Oasis® power supply for one to three filtration pumps—Europe	1	MMPWRSPEU
Milliflex Oasis® power supply for one to three filtration pumps—India	1	MMPWRSPIN
Milliflex Oasis® power supply for one to three filtration pumps—Japan	1	MMPWRSPJP
Milliflex Oasis® power supply for one to three filtration pumps—Switzerland	1	MMPWRSPSZ
Milliflex Oasis® power supply for one to three filtration pumps—United Kingdom	1	MMPWRSPUK
Milliflex Oasis® power supply for one to three filtration pumps—United States	1	MMPWRSPUS
Milliflex Oasis® power supply for one to three filtration pumps—South Africa	1	MMPWRSPZA
Milliflex Oasis® filtration head	1	MMHEADMM2
Milliflex Oasis® filtration head gaskets replacement kit, including gaskets removal tool	5	MMGASKTMM
Milliflex Oasis® filtration head cover set	1	MMHEADCV1
Milliflex Oasis® drain tubing	1	MMDRNTUBE
Milliflex Oasis® internal flow sanitization kit, including one vacuum gauge	1	MMSANKIT1
Milliflex Oasis® internal flow sanitization gasket kit	5	MMGASKTSK
Milliflex Oasis® consumables for internal flow sanitization kit	24	MMSANSYFU
Milliflex Oasis® vacuum gauge for pump performance testing	1	MMGAUGEMM
Milliflex Oasis® electrical cable for connecting two pumps	1	MMCABLEMM
Milliflex Oasis® T connectors for tubings for connecting two pumps	3	MMTCNNECT
Milliflex Oasis® guides for electrical cable and tubing	20	MMTUGUIDE
Milliflex Oasis® membrane support removal tool	1 4	MMSUPREMV
Stickers and filtration head rings for customizing the Milliflex Oasis® pump		MMCUSTKIT
Milliflex® Quantum membrane transfer tool for Milliflex Oasis® system Milliflex® Quantum membrane transfer tool for Milliflex Oasis® gaskets replacement kit	1 5	MMHEADQU1
		MMGASKTQU
Milliflex® Quantum membrane removal tool for all Milliflex® and Milliflex Oasis® devices and media types	1	REMRACKMM
Customer validation protocol format A4	1	MM2PA4VP1
Customer validation protocol format letter	1	MM2PLTVP1

11. Troubleshooting

Issue	Solution
Condensation on media plates	The media plates must be at ambient temperature for optimal growth performance. If plates are stored in a fridge, warming it up to 2 hours is recomended
The pump switch is not active	Check that there is no liquid on the switch
Small amount of liquid in the pump head after filtration	It is normal to observe a small amount of liquid in the pump head, this does not impact the testing results
Large amount of liquid in the pump head after filtration	When filtering a volume larger than the capacity of the filtration unit, the user should complete a proper filtration cycle including the dry out step and continue with the remaining volume(s)—see 3.3 Testing.
Filtration unit leakage	The maximal sample temp is 60 °C (140 °F)
Sample is foaming out of the filtration unit	Use a 250 mL filtration unit
Membrane is broken after filtration	Check the lid position before starting the filtration. If the lid is in closed position while filtering, the membrane might break $$
Long filtration time	Change or check the filtration head gaskets and if issue remains, run a pump performance testing—see section 4.1, Cleaning and maintenance
Sanitization	
Impossible to install the kit	Remove the kit, place it back and turn clockwise—see section 4.7, Pump internal flow sanitization
Leakage when pouring the sterile water	Remove the sanitization funnel and check the position of the funnel gasket
Remaining liquid in the funnel or in the syringe	The test was uncomplete, e.g. due to a power issue during the process. Restart the sanitization from the start

12. Operator & equipment safety instructions

Please refer to the Operator & Equipment instructions addendum on SigmaAldrich.com/Milliflex-Oasis

13. Technical Assistance

For more information visit SigmaAldrich.com/techservice

Standard Product Warranty

The applicable warranty for the products listed in this publication may be found at: **SigmaAldrich.com/terms** (within the "Terms and Conditions of Sale" applicable to your purchase transaction).

MilliporeSigma 400 Summit Drive Burlington, MA 01803

SigmaAldrich.com/milliflex-oasis

