# Dialysis Water Distribution Loop
# Dialysis Concentrate Distribution Loop

# Instructions for Use

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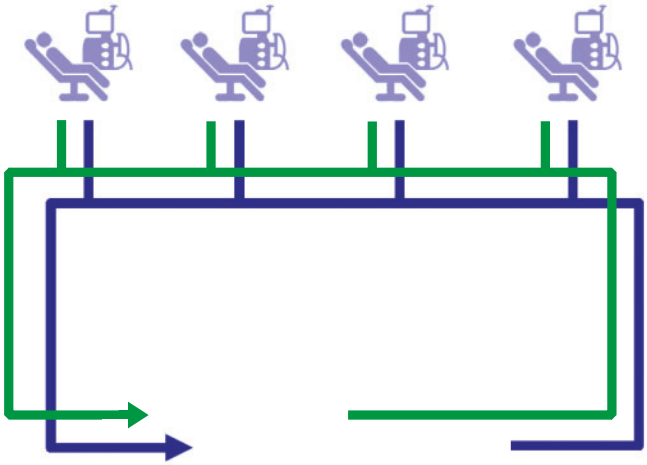

FRESENIUS MEDICAL CARE

# Table of contents

# 1 Index

# 2 Important information

## 2.1 How to use the Instructions for Use

**Description**

In this document, the dialysis water distribution system is referred to as **Dialysis Water Distribution Loop** (**DWDL**) and the dialysis concentrate distribution system is referred to as **Dialysis Concentrate Distribution Loop** (**DCDL**).

**Identification**

The document can be identified by the following information on the title page and on the labels, if any:
- Document edition
- Date of issue of the document
- Document part number

**Footer**

The footer contains the following information:
- Company name
- Product name
- The abbreviation for the document type and the international abbreviation for the document language, e.g., IFU-EN means Instructions for Use in English.
- Edition information, e.g., 04A-2021 means edition 04A from the year 2021
- Page identification

**Organization of the chapters**

To facilitate the use of documents from Fresenius Medical Care, the organization of the chapters has been standardized in all manuals. There may therefore be chapters within this document without any content. Chapters without content are identified.

**Styles used in the document**

The following styles may be used in the document:

| Style | Description |
|---|---|
| ➢ Instruction | Instructions are indicated by an arrow ➢. Instructions must be followed.<br>Example: ➢ Carry out instruction. |

**Illustrations**

The illustrations used in the documents may differ from the original if this does not have any influence on the function.

**Importance of the instructions**

The Instructions for Use are part of the accompanying documents and are an essential part of the **DWDL** and the **DCDL**. They include all information necessary for the use of the distribution systems.

The Instructions for Use must be carefully studied before operational qualification/start-up of the **DWDL** and **DCDL** distribution systems.

**Changes**

Changes to the technical documents will be released as new editions or supplements. In general, this document is subject to change without notice.

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## 2.2 Warnings, significance

Advises the operator that failure to comply with the measures for avoiding the hazard may result in serious or fatal personal injuries.

**Warning**

**Type and cause of the hazard**

Possible consequences if the hazard arises.

➢ Measures for avoiding the hazard.

Warnings can deviate from the example above in the following cases:

– If a warning refers to several hazards.

– If a warning cannot be assigned to one particular hazard.

## 2.3 Notes, significance

**Note**

Advises the operator that failure to observe this information can result in the following:

– Damage to the **DWDL** and **DCDL** distribution systems.

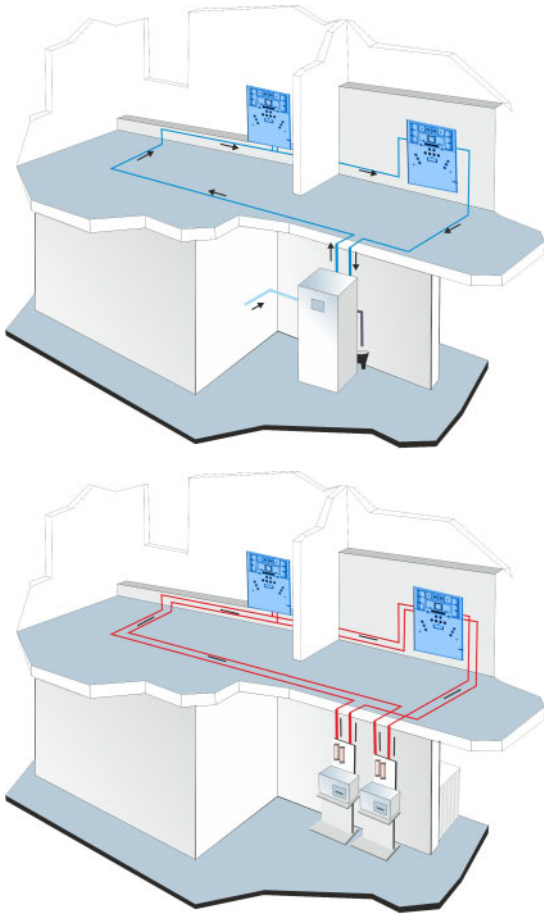
– Specific functions not being executed at all or not being executed correctly

## 2.4 Tips, significance

**Tip**

Information providing useful tips for easy handling.

## 2.5 Brief description



The distribution systems are classified as class IIa (MDR) equipment.

The distribution systems are connection units which can be extended by the responsible organization with additional components to form a complete supply system.

They transport dialysis water via the **Dialysis Water Distribution Loop** distribution system and dialysis concentrate via the **Dialysis Concentrate Distribution Loop** distribution system.

The transported dialysis water can be used for dialysis treatments or for the production of dialysis concentrates. The transported dialysis concentrate can be used for mixing common dialysates.

# 2.6 Intended purpose and related definitions

**Note**

If the distribution system is used in a manner which is not specified by the manufacturer, the quality and characteristics of the dialysis water and dialysis concentrate transported by the distribution system may be impaired.

## 2.6.1 Intended purpose

**Dialysis Water Distribution Loop** (**DWDL**): Central supply of dialysis water

**Dialysis Concentrate Distribution Loop** (**DCDL**): Central supply of dialysis concentrate

## 2.6.2 Medical indication

**DWDL:** Renal insufficiency requiring renal replacement therapy, supported by a central supply of dialysis water.
**DCDL:** Renal insufficiency requiring renal replacement therapy, supported by a central supply of dialysis concentrate.

## 2.6.3 Intended patient population

The distribution systems **DWDL** and **DCDL** do not have a clinical effect of their own. The devices solely transport the dialysis water (**DWDL**), respectively dialysis concentrate (**DCDL**) required for the preparation of standard dialysates. Thus, there are no limitations for an intended patient population. The intended patient population should be defined by the compatible hemodialysis device.

## 2.6.4 Intended user group and intended environment

The distribution systems **DWDL** and **DCDL** must only be installed, operated and used by individuals with the appropriate training, knowledge and experience, and who are certified to have been trained. The distribution systems **DWDL** and **DCDL** must be operated in rooms suitable for the operation of hemodialysis devices located in professional healthcare facilities.

## 2.7 Side effects

There are no side effects that can solely be traced back to the use of dialysis water and dialysis concentrate as they do not have a direct clinical effect on its own. Dialysis water and dialysis concentrate are always used in combination with a hemodialysis treatment. An elevated level of calcium, magnesium and iron in the dialysis water may lead to the hard water syndrome, resulting in nausea, vomiting, asthenia, and/or hypertension.

For reference the following treatment-related side effects known for hemodialysis, as reported in current literature, are listed:

- Acute urticaria
- Anxiety
- Impaired quality of life
- Clotting
- Blood loss
- Depressive symptoms
- Dialysis disequilibrium syndrome
- Thirst
- Vomiting
- Fever
- Hemolysis
- Hypotension
- Itching
- Cardiac arrhythmia
- Headache
- Seizures
- Cramps
- Micro air embolisms
- Cardiac tamponade
- Dialyzer reactions
- Sleep disturbance
- Pain (chest and back)
- Shivering
- Falls
- Nausea
- Restlessness

## 2.8 Contraindications

There are no known contraindications. Dialysis water and dialysis concentrate are never used directly on the patient. Contraindications may exist in the therapy-related context of hemodialysis:

- Hyperkalemia (only with potassium-containing hemodialysis concentrates)
- Hypokalemia (only with potassium-free hemodialysis concentrates)
- Uncontrollable blood-clotting disorders

Relative contraindications (predictors for poor treatment outcome/treatment decision on an individual basis):

– Hypotensive heart failure
– Malignant disease with poor prognosis
– Severe peripheral arterial disease (no access possible)
– Severe mental illness to the extent that patient is not aware of treatment and cannot comply.

A different method of extracorporeal treatment may be indicated for hemodynamically unstable patients.

## 2.9 Residual risks

The central supply of dialysis water and dialysis concentrate via the distribution systems carries a residual risk of microbial contamination, germ growth and the spread of pathogens. Patients may suffer from infection or sepsis.

The use of chemical agents for cleaning and disinfecting the distribution systems entails the residual risk of chemical residues in the dialysis water and dialysis concentrate. Patients may be exposed to toxic or pyrogenic substances.

# 2.10 Interaction with other systems

## 2.10.1 Intended combined use

The medical devices **DWDL** and **DCDL** are intended for use and combination with the following devices:

- **DWDL**
  - **AquaA**
  - **AquaBplus**, **AquaB LITE**
  - **Granumix 107S/507S**
  - **Granumix plus**
  - **MediaP**
  - **MediaC**
  - **MediaR**

- **DCDL**
  - **CDS3**
  - **Granumix plus**
  - **MediaP**
  - **MediaC**
  - **MediaR**

# 2.11 Therapy restrictions

none

# 2.12 Considerations for working on the DWDL and DCDL

**Warning**

**Risk of injury to patients and operators from improper service work on the distribution system**

Improper servicing may impair the safe functioning of the distribution system.

➢ Operational qualification, extensions, maintenance procedures, modifications, or repairs may only be carried out by the manufacturer or by persons authorized by the manufacturer.

To perform the Technical Safety Checks and the maintenance procedures, contact the local service support.

Use only original spare parts. To identify and order spare parts, test equipment, and tools, always use the electronic Spare Parts Catalog.

– Further information on installation (see chapter 9 on page 59).
– Further information about maintenance procedures (see chapter 11.2 on page 66).
– Further information about transport and storage (see chapter 10 on page 63).

## 2.13 Expected service life

The expected service life of the distribution systems is 10 years.

If the maintenance procedures and checks are performed as prescribed and at the defined intervals, the distribution system will run safely between checks.

## 2.14 Duties of the responsible organization

The responsible organization must ensure that the following requirements are met:

– Compliance with the national or local regulations concerning the installation, operation, use, and maintenance of the device.
– Compliance with the accident prevention regulations.
– Ensuring that the distribution system is in proper and safe working order.
– Ensuring that the Instructions for Use are available at all times.
– The distribution system may only be operated under the operating conditions specified by the manufacturer.

### 2.14.1 Further aspects of the responsible organization

The responsible organization must ensure that the technical design of the distribution systems matches the requirements of the other components used to make up the complete system.

The responsible organization must prepare a plan for emergency operation to supply dialysis devices with dialysis water and dialysis concentrate based on the available system components and must make this plan available to the operators of the system.

The responsible organization should inform the local water supplier of the dialysis operation and insist on prior discussion with regards to water composition, availability, etc. This measure does not relieve the responsible organization of its obligation to regularly check the inlet water composition.

Before the responsible organization may start operating the distribution systems, the individual responsible for operation must have been verifiably instructed by the manufacturer in how to use the systems and must be thoroughly familiar with the contents of the Instructions for Use. The manufacturer provides training for distribution systems.

The local service support organization is available to answer any further questions (see chapter 2.20 on page 23).

**Disinfection DCDL**

The **DCDL** is not designed for disinfection.

**Disinfection DWDL**

Bacterial growth in the distribution system depends on the individual components, and the type and time of use. Bacterial growth in the distribution systems must be prevented by continuous operation of the system with a minimum of idle times and by preventive measures such as chemical disinfection or heat disinfection.

Samples for microbial testing must therefore be collected from the distribution system and from the individual parts of the system in accordance with the applicable regulations. As the complete system consists of a number of smaller systems, the responsible organization is responsible for the complete system.

For further information on disinfecting the **DWDL** (see chapter 6.4.1 on page 45).

## 2.15 Operator responsibility

**Warning**

**Risk of injury from defects on the distribution systems**

If the distribution systems have the following defects, the indicated measures must be taken.

**Defects on the distribution systems:**

– Mechanical damage
– Deterioration of performance characteristics: pressure drop, leakages
– Other defects

**Measures:**

– The distribution system must be taken out of service.
– The responsible organization or the local service support must be notified.

### 2.15.1 Reporting incidents

Within EU Member States, the user must report any severe incidents associated with the product to the manufacturer in accordance with the identification as well as the responsible authority of the Member State in which the user is located.

## 2.16 Disclaimer of liability

**Warning**

**Risks affecting the proper functioning of the device**

The distribution system has been approved for use with certain consumables and accessories. Should the responsible organization wish to use other consumables and accessories than those listed in this chapter, the suitability must be checked beforehand by gathering the appropriate manufacturer information. The applicable legal regulations must be complied with.

The manufacturer does not assume any responsibility or liability for personal injury or other damage, and the use of non-approved or unsuitable consumables or accessories resulting in damage to the distribution system will void the warranty.

**Tip**

For further information on the topic of consumables, accessories, additional equipment (see chapter 8 on page 53).

## 2.17 Technical documentation

Descriptions and other technical documents can be provided by the manufacturer on request. These are intended to support appropriately trained personnel of the responsible organization in maintaining and repairing the system.

# 2.18 Warnings

The list of warnings and notes that follows is only an excerpt. Knowledge of all warnings mentioned in this document is required for the safe operation of the distribution systems.

## 2.18.1 Basic warnings

**Warning**

**Undetected fluid leakage outside of dialysis hours**

Leakage can cause damage to buildings.

➢ To prevent damage to buildings outside dialysis hours (unattended times without staff) caused by water leakage, a leakage monitoring system with a shut-off function, such as the **AquaDETECTOR** with leakage sensors, should be installed in every room with supply ports.

➢ If no leakage monitoring system is installed, it is recommended that all supply tubes be disconnected from the distribution system outside dialysis hours (unattended times without staff).

**Note**

The responsible organization must ensure that the Technical Safety Checks (TSC) are performed.

**Warning**

**Risk of injury to patients and operators if the TSC intervals are not complied with**

Non-compliance with the TSC intervals may impair the safe functioning of the distribution system.

➢ The Technical Safety Checks/maintenance procedures (local service) must be performed on the distribution system at least once every 24 months.

➢ The Technical Safety Checks and maintenance procedures may only be performed by certified service technicians with electrical, system-related, and medical-technical knowledge.

**Note**

**Adherence to applicable laws and regulations**

➢ Observe all applicable local laws and regulations concerning the handling of laboratory equipment and reagents.

**Warning**

**Risk of burning and scalding from hot surfaces or hot dialysis water during heat disinfection**

Contact with hot surfaces or hot dialysis water can cause burning or scalding.

➢ Do not touch the accessible components of the dialysis water distribution system while heat disinfection is in progress.

➢ Do not attempt to remove the dialysis water manually while heat disinfection is in progress.

**Warning**

**Undetected fluid leakage due to insufficient checks**

Leakage can cause damage to buildings.

➢ Regular visual inspection and leakage checks of all tubing, connectors, and piping containing fluid are required.

➢ Tubing must be protected against possible mechanical damage.

**Note**

The distribution system is not designed for supporting additional loads.

## 2.18.2 Warnings related to hygiene and biology

**Warning**

**Risk of contamination from unsuitable dialysis water**

There is a risk of spreading germs.

➢ Check the dialysis water quality at regular intervals, and, if necessary, perform the disinfection/cleaning cycles of the dialysis water supply system.

**Warning**

**Risk of poisoning – Not drinking water**

The dialysis water and dialysis concentrate transported via the distribution system do not meet the requirements for drinking water.

**Warning**

**Risk of contamination from insufficient cleaning/disinfection**

There is a risk of spreading germs.

➢ The distribution system may only be cleaned and disinfected by persons who have been instructed on the proper handling of the system during these procedures.

➢ The operator must observe and follow the general safety precautions.

➢ The distribution system may only be disinfected after consultation with the manufacturer of the system or persons authorized by the manufacturer.

**Warning**

**Risk of chemical burns when working with acidic substances (disinfectant / cleaning agent)**

Contact with chemicals can cause chemical burns.

➢ Always handle acidic fluids with care and do not spill any disinfectant concentrate.

➢ Wear appropriate personal protective equipment (gloves, goggles, etc.) in line with the safety precautions for the disinfectant / cleaning agent used.

➢ Observe the safety precautions for the disinfectant / cleaning agent used, including the relevant first aid measures.

**Note**

**Risk of infection**

Observe the applicable local laws and regulations concerning the handling of potentially infectious material.

## 2.19 SVHC (REACH)

Information on the subject of SVHC in accordance with Article 33 of Regulation (EC) 1907/2006 ("REACH") is available from the following website:

www.freseniusmedicalcare.com/en/svhc

## 2.20 Addresses

**Manufacturer**

Fresenius Medical Care AG & Co. KGaA
Else-Kröner-Str. 1
61352 Bad Homburg
GERMANY
Phone: + 49 6172 609-0
www.freseniusmedicalcare.com

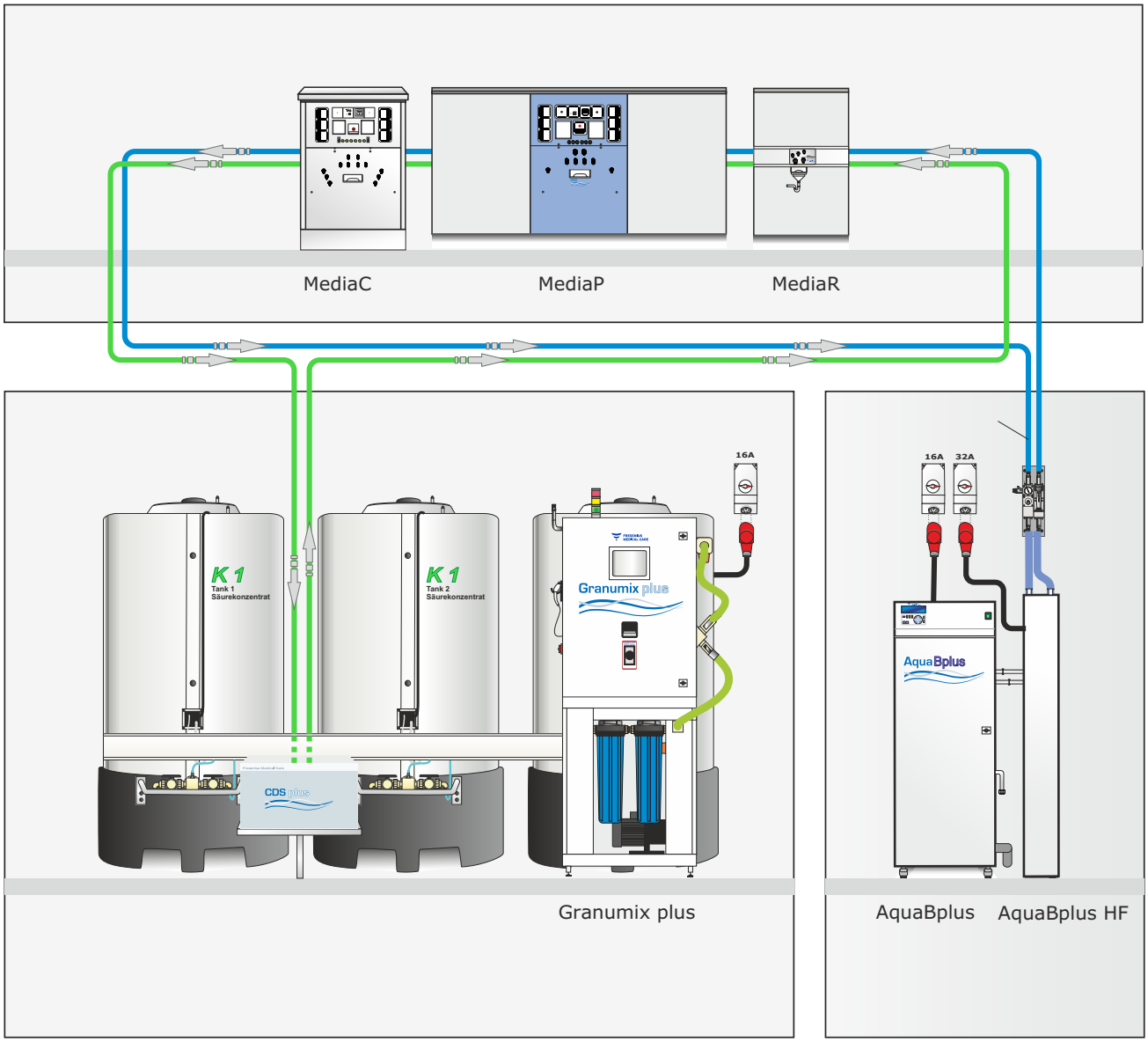
**International service support**

Fresenius Medical Care
Deutschland GmbH
Technical Operations
Technical Coordination Office (TCO)
Hafenstrasse 9
97424 Schweinfurt
GERMANY

**Local service support**

# 3 Structure and views

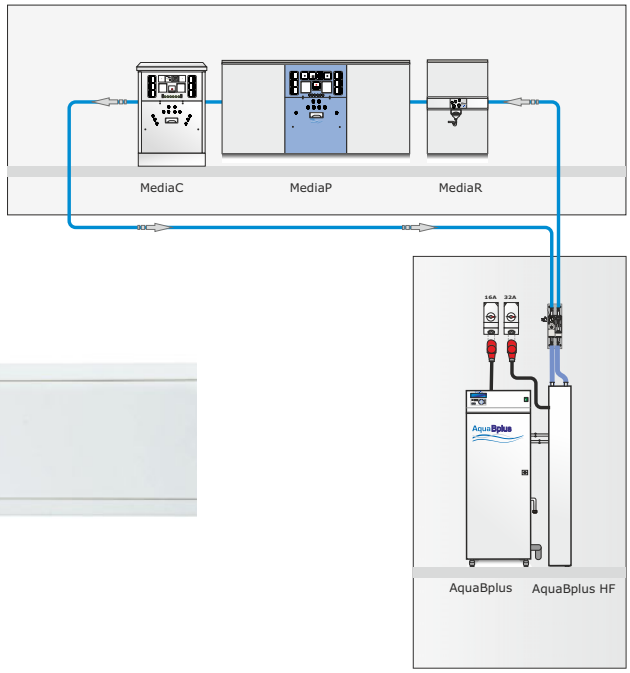
## 3.1 Overall view of the distribution systems




**Legend**

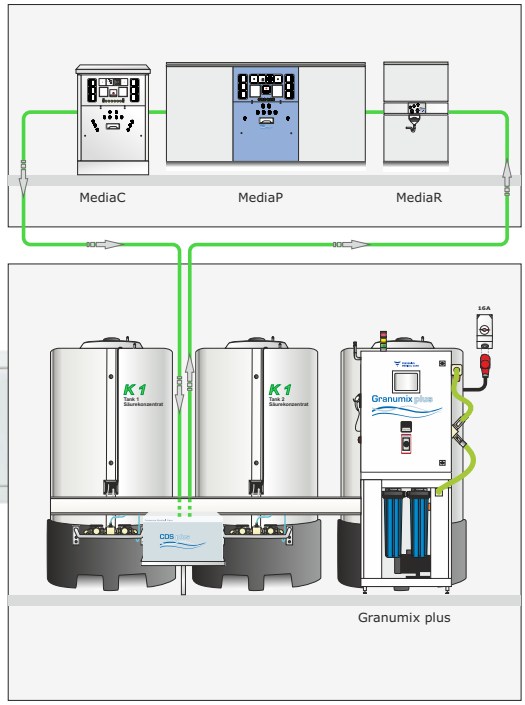
| | |
|---|---|
| **Green** | **Dialysis Concentrate Distribution Loop** (**DCDL**) |
| **Blue** | **Dialysis Water Distribution Loop** (**DWDL**) |

## 3.2 Overall view of DWDL




**DWDL** (Example **MediaR**)


## 3.3 Overall view of DCDL




**DCDL** (Example **MediaR**)

# 4 Operation

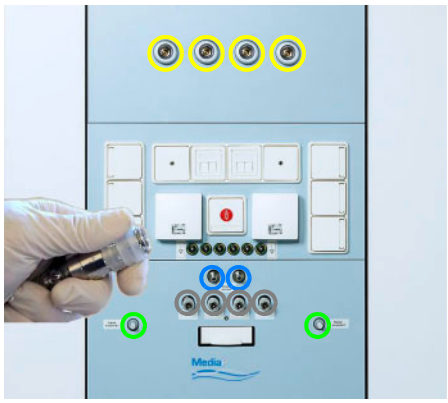
## 4.1 Overview of coupling systems on the media supply systems

### 4.1.1 MediaC


Blue: dialysis water connection

Gray: drain connections

### 4.1.2 MediaP




Yellow: gas connections

Blue: dialysis water connections

Gray: drain connections

Green: dialysis concentrate connections

### 4.1.3 MediaR


Green: dialysis concentrate connections

Blue: dialysis water connection

Gray: drain connection

## 4.2 Observe when operating

**Tip**

➢ For basic information regarding **Definitions**, refer to chapter 13 (see chapter 13.1 on page 71).

**Tip**

➢ For basic information regarding **Product data**, refer to chapter 12 (see chapter 12.1 on page 67).

**Tip**

➢ For basic information regarding **Cleaning and disinfection**, refer to chapter 6 (see chapter 6 on page 41).

## 4.3 Operating the coupling systems

**Warning**

**Patient hazard as a result of a disorder of the electrolyte balance because of a wrong dialysate composition**

Mixing up dialysis concentrates can result in a dialysis fluid that is unsuitable for the patient.

➢ When connecting the hemodialysis device to the media supply system, ensure that the concentrate connections are allocated correctly.

### 4.3.1 To be observed before connecting the hemodialysis device

**Warning**

**Risk of contamination as a result of improper handling of connection sites**

There is a risk of spreading germs.

➢ Before connecting the hemodialysis device to the media supply system, disinfect the couplings and counter-couplings. Observe the Instructions for Use for the hemodialysis device.

➢ It is absolutely essential to avoid contaminating the connections through contact with skin or other non-sterile objects.

**Warning**

**Leakage due to damage on seals**

Leakage can cause damage to buildings.

➢ Before connecting to the corresponding counter-couplings, carefully check all dialysis concentrate couplings for salt crystals and, if necessary, clean and disinfect them. Observe the Instructions for Use for the hemodialysis device.

**Note**

**To be observed before connecting**

➢ The connectors must be disinfected before connecting to prevent possible contamination (see chapter 6.6 on page 48).

**Note**

**Cleaning and disinfecting the connectors**

➢ For information about cleaning and disinfecting the connectors and using the recommended disinfectants, (see chapter 6.5 on page 47) and (see chapter 6.6 on page 48).

### 4.3.2 Connecting and disconnecting

**Warning**

**Risk of leakage as a result of improper handling of the coupling system**

If the lock is not released completely, this can cause increased wear and, as a consequence, fluid leakage.

➢ To connect and disconnect the coupling system, push the sleeve of the lock as far as it will go.


**Recommended equipment** – Rubber gloves

**Step-by step connecting/disconnecting**

➢ Grasp the sleeve of the coupling.

➢ Push the sleeve to the end position and hold it in this position.

➢ Push the coupling as far as it will go onto the nipple and release the sleeve.

➢ Disconnect the coupling by following the connection steps in reverse order.

**Note**

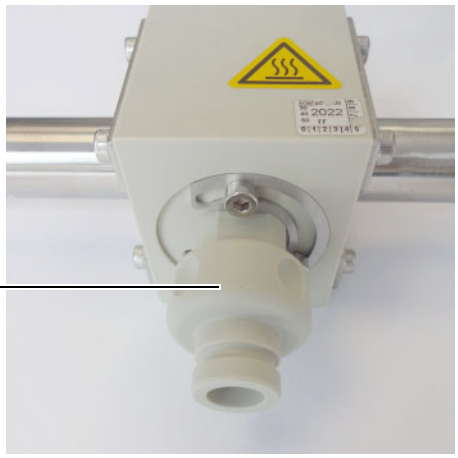
**To be observed during disconnecting:**

➢ Do not place disconnected tubes onto the floor and do not connect with other tubes.

➢ Hang the tubes on a suitable support with the opening pointing down.

# 4.4 Microbiological analysis at the sampling port

The sampling port of the **DWDL** is the sampling valve, which can be opened by turning the valve.




## 4.4.1 Preparation

➢ Have a cooled shipping box available.

➢ The reverse osmosis system must be operated in the **RINSE** or **SUPPLY** mode for at least 20 minutes before the sample is collected.

➢ While collecting the sample, the reverse osmosis system must be in the **RINSE** or **SUPPLY** program.

➢ Collect the sample according to the procedure described for collecting a sample at the sampling port (see chapter 4.4.3 on page 32).

## 4.4.2 Accessories, equipment

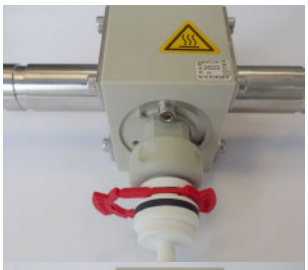
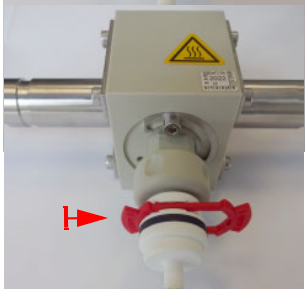
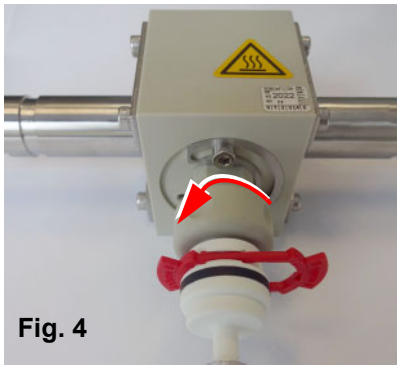
The following equipment is recommended by the manufacturer:

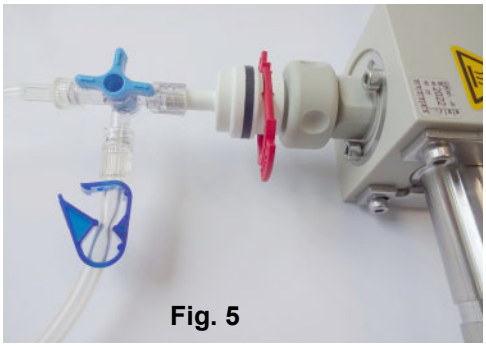
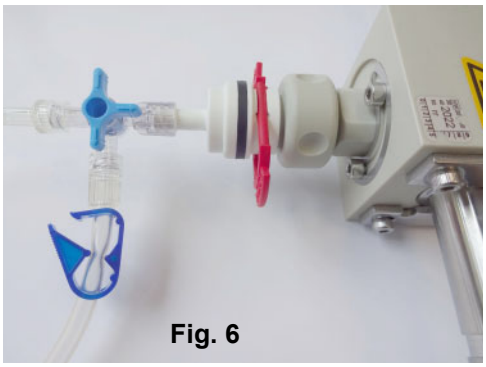
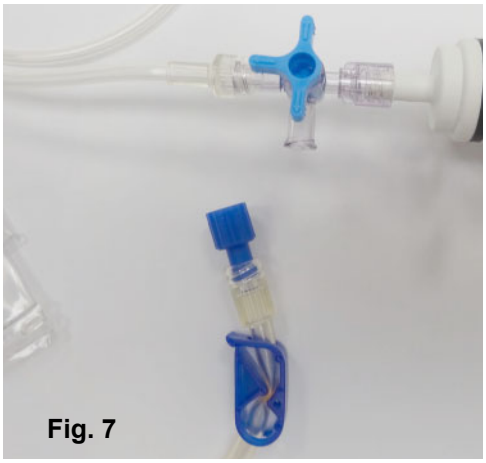
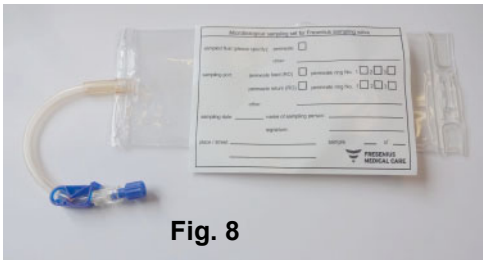
– Rubber gloves

– Alcohol-based disinfectant (approx. 70–80 % alcohol, without lipid replenisher)

The **sampling set for the Fresenius sampling valve** (F00010382) can be used for sampling the dialysis water.

### 4.4.3 Procedure for collecting a sample at the sampling port

| Illustration | Description |
|---|---|
|  <br>**Fig. 1** | **Fig. 1 – Disinfecting the sampling valve:**<br>➢ Disinfect the sampling valve using an alcohol-based disinfectant (without lipid replenisher).<br>➢ Wipe away any contamination using a swab.<br>➢ Then repeat the disinfection procedure (Fig. 1).<br>**Caution:**<br>**Observe the dwell time of the disinfectant!** |
| **Fig. 2**<br>  <br>**Fig. 3**<br>  | **Fig. 2, Fig. 3 – Connecting and locking the adapter:**<br>➢ Place the adapter of the sampling bag onto the sampling valve (Fig. 2).<br>➢ Then lock the adapter (Fig. 3).<br>The multiway valve on the sampling set must be set so as to ensure that no fluid can flow. |
|  <br>**Fig. 4** | **Fig. 4 – Opening the sampling valve**<br>➢ Turn the sampling valve counterclockwise to open it (Fig. 4). |

| Illustration | Description |
|---|---|
|  <br>Fig. 5 | **Fig. 5 – Rinsing the sampling valve**<br>➢ Turn the multiway valve clockwise by 90° to ensure a flow from the adapter to the rinse tubing.<br>➢ Rinse the sampling valve for approx. 60 seconds via the rinse tubing. |
|  <br>Fig. 6 | **Fig. 6 - Filling the bag**<br>➢ Then turn the multiway valve again 90° clockwise to fill the bag.<br>➢ **Caution:**<br>Make sure to return the multiway valve to its locked position in time to prevent the bag from bursting!<br>➢ Close the clamp immediately, release the lock, and remove the bag. |
|  <br>Fig. 7 | **Fig. 7 – Completing the sampling procedure**<br>➢ The sampling valve is now closed again by turning it clockwise.<br>➢ Disconnect the disposable parts after the multiway valve and close the bag **immediately** with the enclosed plug. |
|  <br>Fig. 8 | **Fig. 8 – Preparing the bag for the shipping box**<br>➢ Gently squeeze the bag to check for any leaks.<br>➢ Affix the completed label on the bag and place it into the prepared shipping box.<br>➢ The bag must be delivered to the test laboratory within 24 hours. |

# 4.5 Microbiological analysis at the dialysis water connection

The dialysis water connection on the media supply system serves as the sampling port.


## 4.5.1 Preparation

➢ Have a cooled shipping box available.

➢ The reverse osmosis system must be operated in the **RINSE** or **SUPPLY** mode for at least 20 minutes before the sample is collected.

➢ While collecting the sample, the reverse osmosis system must be in the **RINSE** or **SUPPLY** program.

➢ Disconnect the connection tube of the hemodialysis device from the dialysis water connection of the media supply.

➢ Collect the sample according to the procedure described for collecting a sample for microbiological analysis at the dialysis water connection (see chapter 4.5.3 on page 35).

## 4.5.2 Accessories, equipment

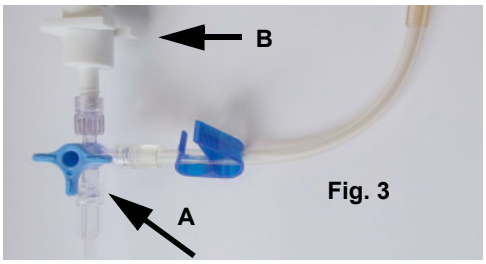
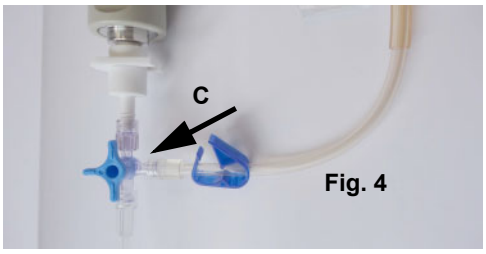
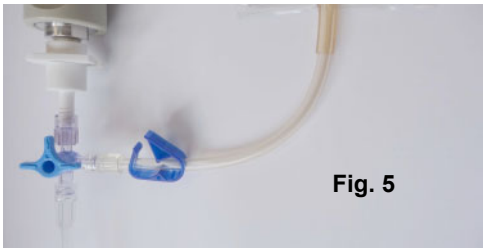
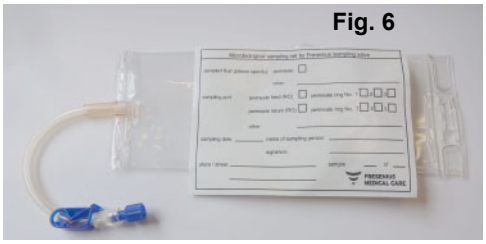
The following equipment is recommended by the manufacturer:

– Rubber gloves

– Alcohol-based disinfectant (approx. 70–80 % alcohol, without lipid replenisher)

– The **bag with adapter** (6030671) can be used for sampling the dialysis water.

### 4.5.3 Procedure for collecting a sample at the dialysis water connection

| Illustration | Description |
|---|---|
|  Fig. 1<br>  Fig. 2 | ➢ Disinfect the dialysis water connection with an alcohol-based disinfectant (Fig. 1) and use a swab to wipe away any contamination (Fig. 2).<br>➢ Then repeat the disinfection procedure (Fig. 1 and 2).<br>**Caution:**<br>**Observe the acting time of the disinfectant!** |
|  Fig. 3<br>  Fig. 4<br>  Fig. 5<br>Fig. 6<br>  | ➢ The multiway valve on the sampling set (**A**) must be set so as to ensure that no fluid can flow (Fig. 3).<br>➢ The adapter of the sampling bag is placed on the dialysis water connection and locked (**B**) (Fig. 3).<br>➢ Then turn the multiway valve 90° clockwise (**C**) and "rinse" the dialysis water connection for approx. 60 seconds via the rinse tubing (Fig. 4).<br>➢ Now turn the multiway valve again 90° clockwise to fill the bag (Fig. 5).<br>➢ After approx. 250 ml (approx. half filled), promptly return the multiway valve to its original position (**A**) (Fig. 3) to prevent the bag from bursting.<br>➢ Close the clamp immediately, release the lock, and remove the bag.<br>➢ Disconnect the disposable parts after the multiway valve and immediately close the bag with the enclosed plug (Fig. 6).<br>Gently squeeze the bag to check for any leaks.<br>Affix the completed label on the bag and place it **immediately** into the prepared shipping box. The bag must be delivered to the test laboratory within 24 hours. |

# 4.6 Collecting a sample for chemical analysis

## 4.6.1 Preparation

Dialysis water consumption is only possible if the reverse osmosis system is in **SUPPLY** mode, or if it is producing dialysis water during a manual rinse program in **RINSE** mode.

Before collecting the sample, the reverse osmosis system must have been in operation for at least 20 minutes. If the device is not in the **SUPPLY** mode, the manual rinse program must be started.

The sample is collected in the **SUPPLY** or **RINSE** mode.

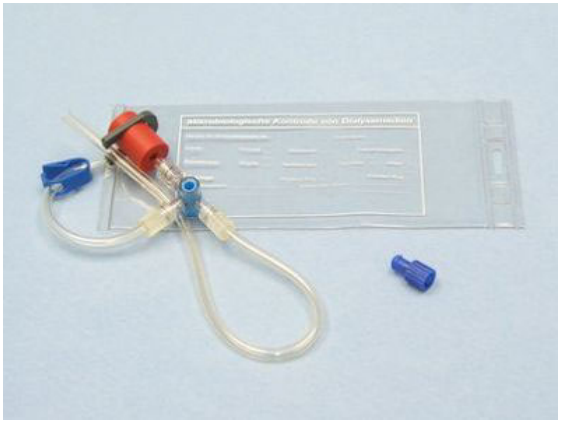
## 4.6.2 Accessories, tools

The following accessories and tools are recommended by the manufacturer:

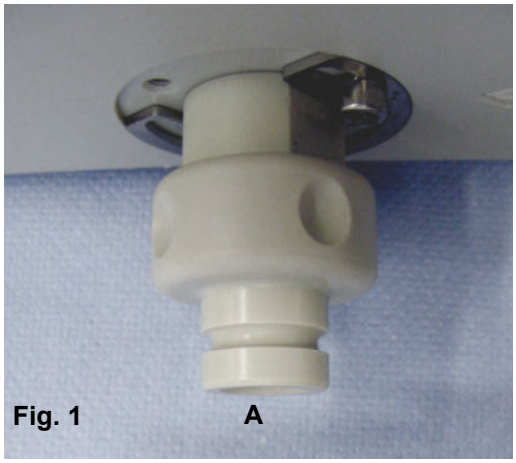
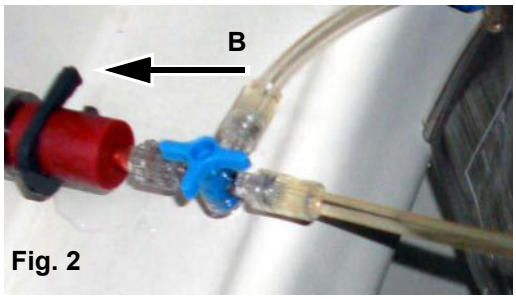
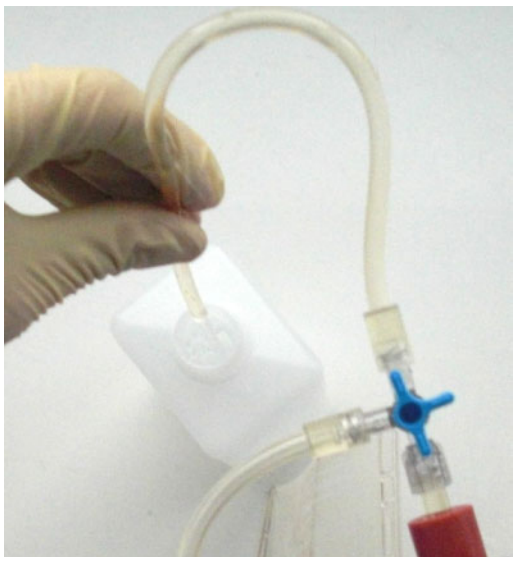
– Rubber gloves

For the chemical sampling, use the sample containers provided by the laboratory.

– For the sampling of the dialysis water, the **bag with adapter** (part no.: 6030671) can be used.



### 4.6.3 Procedure for collecting a sample for chemical analysis

| Illustration | Description |
|---|---|
|  Fig. 1 | ➢ The dialysis water must be collected while the system is in operation (during **SUPPLY**) or after extensive rinsing of the system (see above). Before collecting the sample, rinse the sampling valve **(A or B) (approx. 2–10 L)**.<br>**Caution:**<br>**To avoid contamination of the sample by dirty sample containers, use only the containers supplied by the laboratory!**<br>➢ When collecting the sample, do not open the sample containers until directly before collecting the sample and make sure to close the containers immediately after taking the sample to prevent contamination.<br>➢ The sample containers must be filled up to the top.<br>➢ When collecting a sample the valve must first be sufficiently rinsed **(approx. 5 L)**. Then the sample containers must be filled from the free flowing jet of water. |
|  Fig. 2<br>  | ➢ When collecting the sample on the media supply column, attach the **bag with adapter** to the coupling and fix it in place with the latch (Fig. 2 – B).<br>➢ Then thoroughly rinse the coupling (**approx. 2 L**) via the rinse tubing.<br>➢ Fill the sample container via the rinse tubing.<br>**Caution:**<br>**When collecting a sample at the coupling on the media supply column, do not use the bag with adapter as a sample container.**<br>**Use the bottles supplied by the laboratory as sample containers!** |

# 5 Alarms

This chapter does not contain any content applicable to this product.

# 6 Cleaning, disinfection

## 6.1 Generally applicable regulations for cleaning and disinfection

**Warning**

**Risk of contamination from insufficient cleaning/disinfection**

There is a risk of spreading germs.

➢ The distribution system may only be cleaned and disinfected by persons who have been instructed on the proper handling of the system during these procedures.

➢ The operator must observe and follow the general safety precautions.

➢ The distribution system may only be disinfected after consultation with the manufacturer of the system or persons authorized by the manufacturer.

## 6.2 Precautions

### 6.2.1 Operator safety

**Warning**

**Risk of chemical burns when working with acidic substances (disinfectant / cleaning agent)**

Contact with chemicals can cause chemical burns.

➢ Always handle acidic fluids with care and do not spill any disinfectant concentrate.

➢ Wear appropriate personal protective equipment (gloves, goggles, etc.) in line with the safety precautions for the disinfectant / cleaning agent used.

➢ Observe the safety precautions for the disinfectant / cleaning agent used, including the relevant first aid measures.

**Warning**

**Risk of burning/scalding from hot surfaces or hot dialysis water during heat disinfection**

Contact with hot surfaces or hot dialysis water can cause burning or scalding.

➢ Do not touch the accessible components of the dialysis water distribution system while heat disinfection is in progress.

➢ Do not attempt to remove the dialysis water manually while heat disinfection is in progress.

# 6.3 Surface cleaning, surface disinfection

## 6.3.1 Surface cleaning

If the surface is contaminated by dust and dirt, clean the accessible surfaces of the **DWDL** and **DCDL**.

**Note**

**Surface cleaning agents**

The following procedures must be followed when using cleaning agents:

- ➢ If the **DWDL** and **DCDL** distribution systems are extremely dirty, wipe the affected sections with a damp cloth.
- ➢ Do not use any cleaning agents which contain acetone.
- ➢ Do not use solvents, diluting agents, or chemical cleaning sprays.
- ➢ Do not use any abrasives or aggressive cleaning agents and solvents.
- ➢ Do not use rough cleaning tools (e.g., scouring pad or similar) to clean the **DWDL** and **DCDL** distribution systems.

### 6.3.1.1 Cleaning agents for surfaces

**Tip**

The use of dialysis water is recommended for cleaning surfaces.

## 6.3.2 Surface disinfection

**Note**

The manufacturer recommends using **ClearSurf** for disinfecting the surface of the **DWDL** and **DCDL**.

- ➢ Proceed in accordance with the instructions of the manufacturer of the disinfectant to disinfect the surface.
- ➢ The manufacturer does not assume any liability for potential damage to the surfaces of the **DWDL** and **DCDL** if a different disinfectant than the one recommended is used for disinfection.

#### 6.3.2.1 Surface disinfectant

**Tip**

The use of **ClearSurf** (1 % dilution) or **ClearSurf Wipes** (ready-to-use wipes) is recommended for disinfecting the surfaces.

For further information on disinfectants, refer to the chapter on consumables (see chapter 8.1 on page 54).

# 6.4 Disinfecting the DWDL

## 6.4.1 Reasons for disinfecting the DWDL

If a water supply as specified by the applicable regulations can no longer be ensured:

– After repairs to the dialysis water circuit.

– If the system has been idle for more than 72 consecutive hours.

– ISO 23500-1 "Guidance for the preparation and quality management of fluids for haemodialysis and related therapies" recommends a regular (e.g., monthly) preventive disinfection to avoid significant biofilm formation (biofouling).

– Regular disinfection according to the requirements of the responsible organization

– If a microbiological test reveals an elevated microbial count.

**Recommended disinfectant**

– **Puristeril 340**

or:

– **Puristeril plus**, **Minncare®**

## 6.4.2 Disinfecting the system

**Warning**

**Risk of contamination from insufficient cleaning/disinfection**

There is a risk of spreading germs.

➢ The distribution system may only be cleaned and disinfected by persons who have been instructed on the proper handling of the system during these procedures.

➢ The operator must observe and follow the general safety precautions.

➢ The distribution system may only be disinfected after consultation with the manufacturer of the system or persons authorized by the manufacturer.

**Note**

The system may only be disinfected by trained Clinic Technicians or trained System Technicians who are trained and certified in the appropriate procedures.

- **Performing chemical disinfection**

  The safety precautions, consumables, and operating steps – including performing the residual test – for chemical disinfection are described in the Service Manual of the reverse osmosis systems.

- **Performing heat disinfection**

  The safety precautions and operating steps for heat disinfection are described in the Service Manual of the reverse osmosis systems.

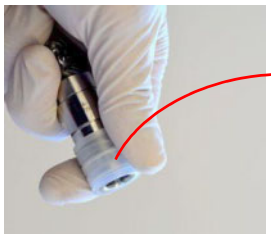
# 6.5 Cleaning connectors and connection ports

The connectors and connection ports are cleaned to remove possible dialysis concentrate residues or salt crystals.

**Recommended equipment**

- Rubber gloves
- Dialysis water
- Small container
- Soft, lint-free cloth or swab

## 6.5.1 Cleaning the connectors



➢ After disconnecting, immerse the connectors in a clean container filled with dialysis water and shake them gently.

➢ Then use a cloth or swab to pat dry the outer surfaces of the connectors.

## 6.5.2 Cleaning the connection ports

**Recommended equipment**

- Rubber gloves
- Laboratory spray bottle with dialysis water
- Soft, lint-free cloth or swab



➢ After disconnecting the couplings, use a laboratory spray bottle filled with dialysis water to rinse the connection ports installed on the media supply system.

➢ Then use a cloth or swab to carefully pat dry the connection ports. Or: Use a damp cloth to carefully clean the connection ports and then pat them dry with a dry cloth or swab.

➢ After the connectors and connection ports have been cleaned, they must be disinfected (see chapter 6.6 on page 48).

## 6.6 Disinfecting connectors and connection ports

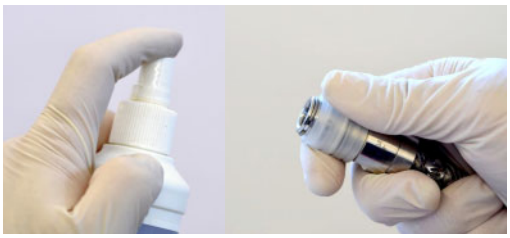
**Recommended equipment**

– Rubber gloves

– Alcohol-based disinfectant (approx. 70–80 % alcohol, without lipid replenisher)

– Soft, lint-free cloth or swab

### 6.6.1 Disinfecting the connectors



➢ After disconnecting, clean the connectors if necessary (see chapter 6.5 on page 47).

➢ Then wet the connectors with an alcohol-based disinfectant. After the dwell time, dry the outer surfaces of the connectors with a cloth or swab or allow the disinfectant to evaporate completely.

**Note**

**To be observed during disconnecting:**

➢ Do not place disconnected tubes onto the floor and do not connect with other tubes.

➢ Hang the tubes on a suitable support with the opening pointing down.

### 6.6.2 Disinfecting the connection ports



➢ After disconnecting the connectors, use a laboratory spray bottle to rinse the connection ports installed on the media supply system and then carefully pat them dry with a cloth or swab.

➢ Then wet them with an alcohol-based disinfectant. After the dwell time, dry the outer surfaces of the connection ports with a cloth or swab or allow the disinfectant to evaporate completely.

# 7 Functional description

This chapter provides a brief functional description of the **DWDL** and **DCDL** distribution systems.

## 7.1 Description of procedures

### 7.1.1 Functions

The distribution systems **DWDL** and **DCDL** are connection units, including the tapping points for the dialysis water (**DWDL**) or dialysis concentrate (**DWDL**), between the reverse osmosis system (**DWDL**) or the concentrate supply system (**DCDL**) and the connected hemodialysis machines. The distribution systems **DWDL** and **DCDL** are used to transport dialysis water (**DWDL**) or dialysis concentrate (**DCDL**).

The trained personnel of the dialysis ward are considered users of the **DWDL** or **DCDL** distribution systems.

Installation and start-up are performed by trained technicians authorized by the manufacturer.

**General functional description of the device**

The **DWDL** is used to connect a reverse osmosis system with either a concentrate supply system or directly with a hemodialysis device in order to transport dialysis water. There is no direct contact with patients.

The **DCDL** distribution system is used to connect a concentrate supply system with a hemodialysis machine in order to transport dialysis concentrate. There is no direct contact with patients.

The **DWDL** or **DCDL** distribution systems are planned and installed according to the local conditions, regarding the length as well as the design and number of installation parts. The **DWDL** and **DCDL** distribution systems are to be regarded as permanently installed units.

# 8 Consumables, accessories, and additional equipment

**Warning**

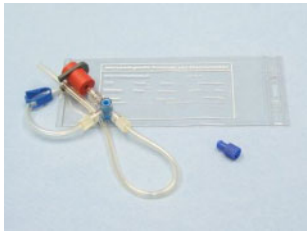
**Risks affecting the proper functioning of the device**

The distribution system has been approved for use with certain consumables and accessories. Should the responsible organization wish to use other consumables and accessories than those listed in this chapter, the suitability must be checked beforehand by gathering the appropriate manufacturer information. The applicable legal regulations must be complied with.

The manufacturer does not assume any responsibility or liability for personal injury or other damage, and the use of non-approved or unsuitable consumables or accessories resulting in damage to the distribution system will void the warranty.

Upon request the local service support will provide information about further accessories, consumables, and other additional equipment.

# 8.1 Consumables

| Part number | Consumables | Figure |
|---|---|---|
| **5085851** | **Puristeril plus**<br>Active substance: Peracetic acid; D, GB, DK, E, FIN, I, NL, S | n/a |
| **5085671** | **Puristeril 340**<br>Active substance: Peracetic acid; D, GB, DK, E, FIN, I, NL, S | n/a |
| **n/a** | **Minncare®** | n/a |
| | | |
| **6030711** | **ClearSurf concentrate**<br>(or: **ClearSurf wipes**)<br>Surface disinfectant | n/a |
| | | |
| **6299161** | **Peracetic acid test**<br>5–50 mg/L | n/a |
| | | |
| **6030671** | **Bag with adapter**<br>Sampling set for standard configuration |  |
| **F00010382** | **Sampling set for the Fresenius sampling valve**<br>Sampling set for dialysis water distribution systems |  |

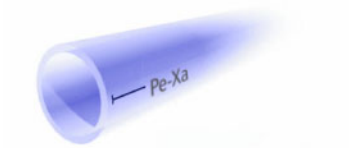
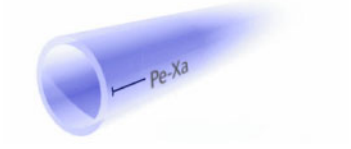
# 8.2 Accessories

## 8.2.1 Accessories for the DCDL distribution system

| Part number | Description | Information |
|---|---|---|
| **6309241** | **Tube PE white**<br>8 x 12 mm white; length 100 m;<br>Intended for concentrate type K1 | Contact with dialysis concentrate<br>  |
| **M512671** | **Tube PE red**<br>8 x 12 mm; length 100 m;<br>Intended for concentrate type K2 | Contact with dialysis concentrate<br>  |
| **M512681** | **Tube PE blue**<br>8 x 12 mm; length 100 m;<br>Intended for concentrate type K3 | Contact with dialysis concentrate<br>  |
| **5453721** | **Reinforced tube, white**<br>D6 mm | Contact with dialysis concentrate |
| **F40005702** | **Double nozzle**<br>D8 mm; PPSU | Contact with dialysis concentrate |
| **n/a** | **O-ring EPDM**<br>4 x 4 mm | Part of the **MediaR**, **MediaC**, **MediaP** |
| **n/a** | **Nipple, closure conc.**<br>DN4, G1/4", PPSU | Part of the **MediaR**, **MediaC**, **MediaP** |
| **n/a** | **Nipple, closure conc.**<br>DN4, G1/4", PVDF | Part of the **MediaR**, **MediaC**, **MediaP** |
| **F00010505** | **Concentrate nipple**<br>PPSU; including seal | Contact with dialysis concentrate |
| **F00010506** | **Concentrate nipple**<br>PVDF; including seal | Contact with dialysis concentrate |
| **F40005755** | **Concentrate block K0**<br>**MediaR** | Contact with dialysis concentrate |
| **F00010855** | **Concentrate module**<br>**MediaR**; including nozzles | Contact with dialysis concentrate |

| Part number | Description | Information |
|---|---|---|
| **n/a** | **Concentrate block**<br>0–0° | Part of the **MediaC**, **MediaP** |
| **F00010501** | **Concentrate block 2 x straight**<br>**MediaC**, **MediaP** | Contact with dialysis concentrate |
| **F00010502** | **Concentrate unit K1 double**<br>**MediaC**, **MediaP**; modular system | Contact with dialysis concentrate |
| **F00010503** | **Concentrate unit K2 double**<br>**MediaC**, **MediaP**; modular system | Contact with dialysis concentrate |
| **F00010504** | **Concentrate unit K3 double**<br>**MediaC**, **MediaP**; modular system | Contact with dialysis concentrate |
| **F40005704** | **Concentrate block**<br>45–0° | Contact with dialysis concentrate |
| **F40005705** | **Concentrate block**<br>0–45° | Contact with dialysis concentrate |
| **M026391** | **Tube clamp**<br>Single; 14.5 mm | No contact with dialysis concentrate |

### 8.2.2 Accessories for the DWDL distribution system

| Part number | Description | Information |
|---|---|---|
| **6345031** | **XLPE tube, natural**<br>25 x 3.5 mm (100 m distribution) | Contact with dialysis water<br>  |
| **6309351** | **XLPE tube, natural**<br>25 x 3.5 mm (50 m distribution) | Contact with dialysis water<br>  |
| **6316031** | **Connector 90°**<br>Stainless steel for PEX tube 25 x 3.5 mm | Contact with dialysis water |
| **6316041** | **Connector, straight**<br>Stainless steel for PEX tube 25 x 3.5 mm | Contact with dialysis water |
| **6325801** | **PEX connector 180°**<br>U-connector for stainless steel cable duct | Contact with dialysis water |
| **n/a** | **Dialysis water connection, straight**<br>MSM PEX double with connecting element | Part of the **MediaC**, **MediaP** |

| Part number | Description | Information |
|---|---|---|
| **n/a** | **Dialysis water connection, double, straight**<br>MSM PEX double with connecting element | Part of the **MediaC**, **MediaP** |
| **F00007306** | **Dialysis water supply center**<br>Double arch **MediaC**, single | Contact with dialysis water |
| **F00007307** | **Dialysis water supply center**<br>Double arch **MediaC**, double | Contact with dialysis water |
| **F00006458** | **Fluid Fly Loop**<br>Secondary ring main 2 x 2 m, strain relief, ring nut, device connection, nipple with sample collection | Contact with dialysis water |
| **F00006459** | **Fluid Fly Loop**<br>Secondary ring main 2 x 2 m, strain relief, ring nut, device connection, nipple without sample collection | Contact with dialysis water |
| **n/a** | **Flat gasket**<br>EPDM; 11.5 x 5 x 3.6 | Part of the **MediaR**, **MediaC**, **MediaP** |
| **n/a** | **Nipple closure**<br>NW 6-G 1/4" 11 mm dialysis water | Part of the **MediaC**, **MediaP** |
| **n/a** | **Nipple closure**<br>NW 6-R 1/4" 11 mm dialysis water | Part of the **MediaR** |
| **F00010499** | **Dialysis water nipple**<br>Walther incl. seal | Contact with dialysis water |
| **F00010500** | **Dialysis water nipple**<br>FIDICA incl. seal | Contact with dialysis water |
| **F00010492** | **Dialysis water block**<br>**MediaC**, **MediaP** single, straight | Contact with dialysis water |
| **F00010493** | **Dialysis water block**<br>**MediaC**, **MediaP** double, straight | Contact with dialysis water |
| **F00010494** | **Dialysis water block stainless steel**<br>**MediaC**, **MediaP** single – 2 x 90° angled – modular system | Contact with dialysis water |
| **F00010495** | **Dialysis water block stainless steel**<br>**MediaC**, **MediaP** double – 2 x 90° angled – modular system | Contact with dialysis water |
| **F00010826** | **Dialysis water module**<br>**MediaR** | Contact with dialysis water |
| **F00010873** | **PEX connection, long (set),**<br>Dialysis water block **MediaR** – modular system | Contact with dialysis water |
| **6309401** | **Sleeve**<br>25 x 3.5 mm | No contact with dialysis water |

# 8.3 Additional equipment

## 8.3.1 Additional equipment for the DWDL distribution system

| Part number | Description | Information |
|---|---|---|
| **F40001179** | **Sampling set**<br>PE-Xa | Contact with dialysis water |
| **F00010866** | **Lock washer 19**<br>Dialysis water **MediaC**, **MediaP**, with fixing | No contact with dialysis water |
| **F00010507** | **Lock washer 19**<br>Dialysis water/waste water **MediaR**, with fixing | No contact with dialysis water |

## 8.3.2 Additional equipment for the DCDL distribution system

| Part number | Description | Information |
|---|---|---|
| **F00010869** | **Lock washer 17**<br>Dialysis concentrate **MediaC**, **MediaP**, with fixing | No contact with dialysis concentrate |
| **F00010508** | **Lock washer 17**<br>Dialysis concentrate **MediaR**, with fixing | No contact with dialysis concentrate |

# 9 Installation

## 9.1 Installation requirements

### 9.1.1 General information

**Follow the applicable installation guidelines**

For new installations, the applicable installation guidelines must be followed.

**To be observed before the operational qualification**

The operational qualification of the distribution systems is performed together with the operational qualification of the supplying devices.

**Observe national and local regulations**

The national or local installation, operation, use, and maintenance regulations must be complied with.

**State of components**

Prior to installation, check the components of the distribution systems for damage that may have occurred during transport.

**Note**

**Protecting components containing fluid**

➢ Prior to operational qualification, check the components of the distribution system for damage that may have occurred during transport. If there are signs of damage to the hydraulic components, do not use the distribution system.

**Access to the connection points**

The connection points of the distribution systems must be accessible for checks.

**Performance parameters of connected devices**

The performance parameters of the connected device must be taken into account when designing the distribution system. For further information, see the Service Manuals of the supplying devices.

### 9.1.2 Environmental conditions

**Observe the local conditions**

– The installation site must be free from frost and dust.
– The components must not be exposed to continuous, direct sunlight.

### 9.1.3 Structural installation requirements

**Leakage sensor**

The use of a leakage sensor is recommended.

**Pilot holes**

The hole pattern with hole sizes and distances must be applied. For further information, the Installation Guideline (IGL) must be followed.

# 9.2 Operational qualification

## 9.2.1 To be observed before the operational qualification

**Tester's qualification**

Operational Qualification must be performed by the technical service department of Fresenius Medical Care or a person authorized by them.

The Operational Qualification may only be performed by persons qualified to properly perform the specified checks based on their educational background, training, knowledge, and experience. Furthermore, the persons performing the checks must not be bound by any directives when performing this activity.

**For operational qualification only**

The following information is only intended for the operational qualification. It is not applicable to the operational requalification of **DWDL** and **DCDL** distribution systems that have been decommissioned or temporarily decommissioned.

**Specifications**

– Observe the information on the specifications.
– Specific connection and performance data must be taken from the Specifications chapter.

**Use of spare parts**

Any installation, modification, or repair work requiring the **DWDL** and **DCDL** to be opened may only be performed by manufacturer-authorized persons and is permitted only when using original spare parts.

**Identification of supply ports**

Identification of the distribution system supply ports:

– Dialysis water
– Dialysis concentrate (C1, C2, C3)

**Test equipment and tools**

The activities described in this document require the availability of the necessary technical test equipment and tools.

**Maintenance procedures (MA)**

For further information (see chapter 11.2 on page 66).

**Note**

All local regulations regarding technical safety must be observed.

**Precautions**

Repair any visible damage.

## 9.2.2 Operational Qualification procedure

**Note**

➢ When performing the operational qualification on the distribution systems, the descriptions in the Service Manual must be followed.

- **After Operational Qualification**

**Warning**

**Risk of contamination from insufficient cleaning/disinfection**

Before start-up, a chemical disinfection must be performed on the **DWDL**. The successful disinfection must be verified by means of a microbiological analysis.

**Note**

➢ The senior physician must be informed about the results of the microbiological analysis. The Technical Safety Checks must be performed and reported.

## 9.3 Removal from service, decommissioning

**Note**

➢ For information regarding the removal from service or decommissioning of the **DWDL** and **DCDL** distribution system, contact the local service support.

### 9.3.1 Removal from service

**Note**

If the **DWDL** and **DCDL** distribution systems are removed from service after the operational qualification, the following has to be observed:

➢ On operational requalification, the water supply pressure must be checked against the prescribed minimum pressure.

### 9.3.2 Decommissioning

**Note**

➢ For information regarding decommissioning of the **DWDL** and **DCDL** distribution systems, contact the local service support.

# 10 Transport and storage

**Note**

The following transport and storage conditions and further information regarding transport and storage affect the **DWDL** and **DCDL** distribution systems.

## 10.1 Transport and storage conditions

**Storage temperature range** 5 to 45 °C

**Note**

Protect the **DWDL** and **DCDL** distribution systems from frost.

**Relative humidity** 20 to 80 % at 20 °C (non-condensing)

**Atmospheric pressure** 700 hPa to 1150 hPa

**Note**

**Protection from exposure to UV light**

Do not expose the components of the distribution system to direct sunlight (UV rays may cause premature aging of the materials).

➢ Do not store outdoors!

## 10.2 Environmental compatibility/disposal

In the EU member states, the **DWDL** and **DCDL** can be returned to the manufacturer. Please also observe the applicable local legal regulations.

Before the device is sent off for disposal, the responsible organization must ensure that all consumables attached to the **DWDL** and **DCDL** are removed and the **DWDL** and **DCDL** are disinfected as specified by the manufacturer (see chapter 6 on page 41).

The responsible organization must also inform the disposal company responsible for dismantling and disposing of the **DWDL** and **DCDL** of the following before the start of the disposal measures:

– It is possible that the **DWDL** and **DCDL** distribution systems may be contaminated when returned. Therefore, it is vital to take suitable precautions when dismantling it, such as wearing personal protective equipment.

– Further information will be provided if requested by disposal companies.

### 10.2.1 Handling of disinfectants

It is absolutely essential to observe the manufacturer's specifications of the disinfectants used (relating to protective clothing, storage, dosing, expiration date).

The local regulations with regard to the disposal of waste water, if defined, must be clarified and observed before using disinfectants.

# 11 Technical Safety Checks and maintenance

## 11.1 Important information for performing the TSC/MA

**Checks**

The Technical Safety Checks (TSC) must be performed every 24 months.

**Tester's qualification**

The checks must be performed by the manufacturer's service support or a manufacturer-authorized person.

The checks may only be performed by persons qualified to properly perform the specified checks owing to their educational background, training, knowledge, and experience. Furthermore, the persons performing the checks must not be bound by any directives when performing this activity.

**Specifications**

Observe the information on the specifications.

**Documentation**

➢ To perform the Technical Safety Checks (TSC) and the maintenance procedures (MA), contact the local service support.

➢ Performance of the Technical Safety Checks must be entered in the Medical Device Register.

# 11.2 Maintenance procedures

The following procedures must be performed by the operator in accordance with the specifications regarding intervals.

## 11.2.1 Quality assurance and care measures

| Action | Accessories/target state | Interval | Comment |
|---|---|---|---|
| **Cleaning and disinfection measures** | ➢ Surface cleaning or surface disinfection<br>➢ Cleaning or disinfecting the connectors and connection ports | **Recommendation:**<br>**When required** | (see chapter 6.3 on page 43), (see chapter 6.5 on page 47), (see chapter 6.6 on page 48) |
| **Visual inspection and leakage check** | ➢ Perform a visual inspection of all connectors and tubing containing fluid. | **Daily** | (see chapter 4.3.1 on page 28) |

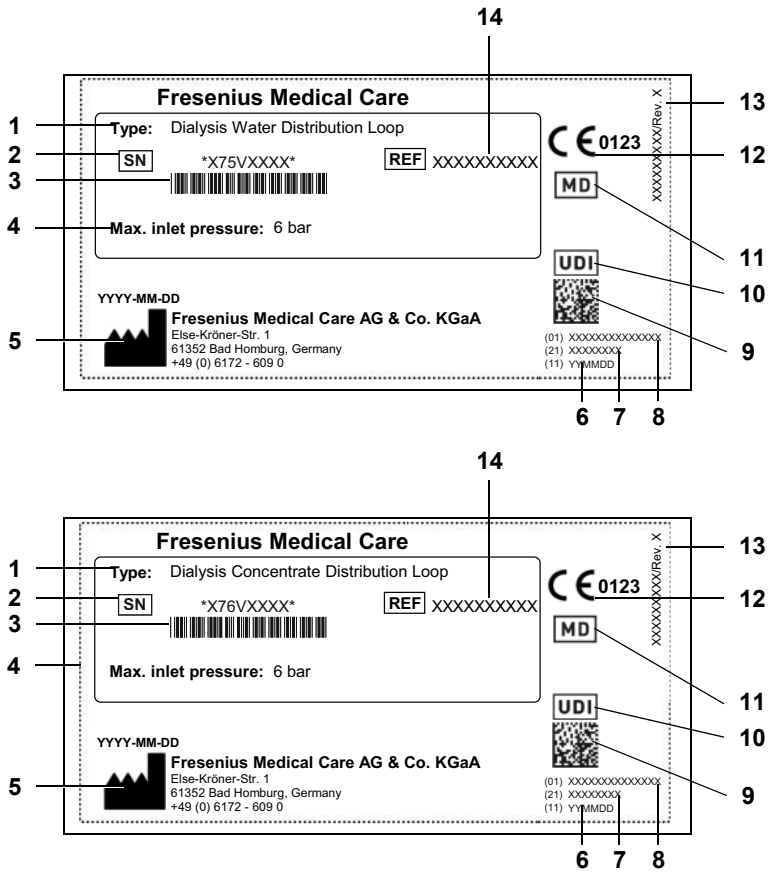
# 12 Specifications

## 12.1 DWDL and DCDL product data

| Specifications | DWDL | DCDL |
|---|---|---|
| **Dimensions**<br>Internal diameter (mm)<br>Wall thickness (mm)<br>External diameter (mm) | 25 x 3.5 mm<br>18.0<br>3.5<br>25.0 | 12 x 2 mm<br>8.0<br>2.0<br>12.0 |
| **Weight (kg)** | depending on the project planning | |
| **Material** | Polyethylene, cross-linked | Low-density polyethylene (LDPE) |
| **Medium** | Dialysis water according to ISO 23500-3 | Dialysis concentrate according to ISO 23500-4:<br>– Acetate-based, acidic dialysis concentrates<br>– Citrate-based, acidic dialysis concentrates |
| **Operating conditions** | | |
| **Operating pressure** | 0–6 bar | |
| **Operating temperature range** | 5–35 °C | 5–30 °C |
| **Atmospheric pressure** | 700 hPa to 1150 hPa | |
| **Relative humidity** | 20 to 80 % at 20 °C (non-condensing) | |
| **Medium operating temperature** | 5–35 °C | 5–30 °C |
| **Maximum temperature during heat disinfection** | 95 °C | -- |
| **Transport and storage conditions** | | |
| **Storage temperature range** | 5 to 45 °C | |
| **Atmospheric pressure** | 700 hPa to 1150 hPa | |
| **Relative humidity** | 20 to 80 % at 20 °C (non-condensing) | |
| **ISO standards** | ISO 23500-1<br>ISO 23500-2<br>ISO 23500-3 | ISO 23500-1<br>ISO 23500-4 |
| **Materials used** | According to ISO 10993-1 | |
| The **DWDL** and **DCDL** distribution systems are planned and installed according to the local conditions regarding the length as well as the design and number of installation parts. The **DWDL** and **DCDL** distribution systems are to be regarded as permanently installed units. | | |

# 12.2 Identification label (DWDL and DCDL identification)

The identification label shown is only an example. The actual data is the data specified on the identification label of the **DWDL** and the **DCDL**.




**1** Type identification
**2** Serial number
**3** Barcode, Code 39
**4** Max. inlet pressure
**5** Manufacturer: date of manufacture and manufacturer's address
**6** (11) Date of manufacture YYMMDD, 6 digits
**7** (21) Serial number, 8 digits
**8** (01) *GTIN (**SAP: EAN/UPC code), 13 digits plus digit 0
**9** ***UDI scan code
**10** UDI identification
**11** Medical device identification
**12** CE mark
**13** Part number and identification label edition
**14** REF = SAP material number

*GTIN = **G**lobal **T**rade **I**tem **N**umber
**SAP: EAN/UPC code = SAP product code: **E**uropean **A**rticle **N**umber/**U**niversal **P**roduct **C**ode
***UDI = **U**nique **D**evice **I**dentification

## 12.3 Transport/storage

For further information, (see chapter 10 on page 63).

## 12.4 Materials used

For further information, (see chapter 12.1 on page 67).

# 13 Definitions

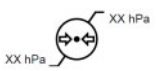
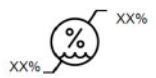
## 13.1 Definitions and terms

| | |
|---|---|
| **Coupling system** | Hydraulic, mechanical connections establish the connection between the hemodialysis system and the dialysis media supply system. |
| **Dialysate, dialysis fluid** | The exchange fluid used in dialysis. |
| **Dialysis concentrate** | Dialysis concentrate is a highly concentrated solution consisting of solid and/or liquid components and dialysis water. Dialysis concentrate is used in the hemodialysis device with other components for the production of dialysis fluid. |
| **Dialysis concentrate distribution system** | Transport line which provides dialysis concentrate for use in dialysis units. |
| **Dialysis water** | Water suitable for dialysis treatments (water processed by a reverse osmosis system which meets the requirements of ISO 23500-3). A high-pressure pump, membrane module, and appropriate monitoring equipment are used to produce dialysis water from drinking water. |
| **Dialysis water distribution system** | Transport line which provides dialysis water for use in dialysis units. |
| **Initial operational qualification** | Initial start-up |
| **Media supply system** | Main interface and connection unit between the hydraulic lines such as dialysis water supply line, dialysis concentrate supply line, drainage line, and the hemodialysis system. |
| **Operational qualification** | Start-up |
| **Operational requalification** | Recommissioning |
| **Permeate** | This term is used as a synonym for dialysis water. This term must only be used in a technical context. |

## 13.2 Abbreviations

| | |
|---|---|
| **C1** | Dialysis concentrate 1 |
| **C2** | Dialysis concentrate 2 |
| **C3** | Dialysis concentrate 3 |
| **DCDL** | **Dialysis Concentrate Distribution Loop** |
| **DWDL** | **Dialysis Water Distribution Loop** |
| **Fig.** | Figure (diagram) |
| **MA** | Maintenance |
| **REACH** | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| **RO** | Reverse osmosis system |
| **SVHC** | Substance of Very High Concern |
| **TSC** | Technical Safety Checks |

## 13.3 Symbol

| Symbols | Description |
|---|---|
| CE 0123 | The CE mark documents compliance with the MDR; notified body: TÜV PRODUCT SERVICE 0123 |
|   | Year/month/day of manufacture |
| SN | Serial number |
| MD | Medical device |
| REF | Material number |
| UDI | **U**nique **D**evice **I**dentification |
|  | Follow the Instructions for Use! |
|  | eIFU, www.freseniusmedicalcare.com/en/product-information-fme |
|  | Caution! Do not stack! |
|  | Do not use hooks! |
|  | Store upright! Do not tilt! |
|  | Caution: Fragile |
|  | Keep dry! |
|  | Warning: Hot surface |
|   | Permissible temperature range |
|   | Atmospheric pressure operating conditions range |
|   | Relative air humidity operating conditions range |
|  | Protect against sunlight (UV light)! |

## 13.4 Certificates

Upon request the local service support will provide the currently valid versions of the certificates.

# 14 Options

This chapter does not contain any content applicable to this product.

# 15 Appendix

## 15.1 Medical Device Register for the DWDL and DCDL

### 15.1.1 Responsible organization and identification

The following page shows the master copy of the address of the responsible organization and the product identification.

| Dialysis Water Distribution Loop, Dialysis Concentrate Distribution Loop | **Address of the responsible organization & identification** | FRESENIUS MEDICAL CARE |
|---|---|---|

| **Address of the responsible organization** |
|---|
| Name: |
| Address: |
| City: |
| Phone: |
| Site of installation |

| **Internal medical consultant** |
|---|
| Name, phone: |
| Name, phone: |
| Name, phone: |
| Name, phone: |
| Name, phone: |

| **Identification** |
|---|
| **DWDL, DCDL** |
| **Type:** Dialysis water and dialysis concentrate |
| **Classification:** IIa |
| **Registration number:** |
| **Identification number of the certified body:** 0123 |
| **Serial number:** |
| **Flexible insulation** available; yes ❑, no ❑ |
| **Manufacturer:** Fresenius Medical Care & Co. KGaA, 61352 Bad Homburg |

| **Tests and checks** | |
|---|---|
| **Type** | **Intervals** |
| Technical Safety Check (TSC) | Every 24 months |
| _____ | Every _____ months |
| _____ | Every _____ months |

| **Contracts regarding tests and checks:** |
|---|
| **Technical Safety Checks:** |
| Company name: |
| Address: |
| Phone: |

### 15.1.2 Contents of the Medical Device Register for the DWDL and DCDL

The following page shows the contents of the Medical Device Register for the **DWDL** and **DCDL** distribution systems.

| Dialysis Water Distribution Loop, Dialysis Concentrate Distribution Loop | **Contents of the Medical Device Register** | FRESENIUS MEDICAL CARE |
|---|---|---|

| | |
|---|---|
| **1** | **Instructions for Use** |
| **Monitoring** | |
| **2** | **Microbiological and chemical monitoring for DWDL**<br>– Results of the microbiological analysis<br>– Results of the chemical analysis<br>– Sampling plans |
| **3** | **Settings reports** |
| **4** | **Service reports, device training, malfunctions**<br>– Device Training Record<br>– Service reports and documentation of modifications to the device equipment<br>– Reporting of incidences<br>– Documentation of malfunctions and repeated, identical operating errors |
| **5** | **Technical Safety Checks (TSC) and revalidation** |
| **Validation phase** | |
| **6** | **Installation qualification (IQ)**<br>– Installation report<br>– Validation plan |
| **7** | **Operational qualification (OQ)**<br>– Training record OQ<br>– Sampling plan OQ<br>– Disinfection plan OQ<br>– Start-up report OQ |
| **8** | **Performance qualification (PQ)**<br>– Results of the microbiological analysis PQ<br>– Results of the chemical analysis PQ |

## 15.2 Training Record

**Applicability, purpose**

The responsible organization must ensure that operators receive proper instruction. Operator instruction is based on the Instructions for Use and, if present, the enclosed Additional Sheets. The manufacturer recommends using this Training Record to document the operator instruction performed.

**Significance of the warnings**

Observing all warnings in the Instructions for Use is essential for using the device safely. Instruction must be given on all warnings in the Instructions for Use.

- **Explanations on the Training Record report**

General information

- The report heading records the circumstances of operator instruction.
- The report footer records the trainer and participants.
- The chapters of the Instructions for Use are listed on separate lines up to the second level.

Y/N/NA

- ❑/–/– Chapter required for proper operator instruction.
- ❑/❑/– Chapter recommended for proper operator instruction.
- ❑/–/❑ If option is available: Chapter required for proper operator instruction.
- ❑/❑/❑ If option is available: Chapter recommended for proper operator instruction.

➢ Record the instruction of the relevant content and warnings completed by marking ✔ in field **Y**.

➢ Record chapters or options that have not been instructed with ✔ in field **N**.

➢ Record unavailable options with ✔ in field **NA**.

| FRESENIUS MEDICAL CARE | **Training Record** | **DWDL** and **DCDL** |
|---|---|---|
| Customer name: | | Start date: |
| Address: | | End date: |
| Customer name: | | Software version: n/a |
| Serial number **DWDL** 1: | | |
| Serial number **DWDL** 2: | | |
| Serial number **DWDL** 3: | | |
| Serial number **DCDL** 1: | | |
| Serial number **DCDL** 2: | | |
| Serial number **DCDL** 3: | | |

| **Description** | | **Y/N/NA** |
|---|---|---|
| **1** | **Index** | |
| **2** | **Important information** | |
| 2.1 | How to use the Instructions for Use | ❑/❑/– |
| 2.2 | Warnings, significance | ❑/–/– |
| 2.3 | Notes, significance | ❑/❑/– |
| 2.4 | Tips, significance | ❑/❑/– |

| Description | | Y/N/NA |
|---|---|---|
| 2.5 | Brief description | ❑/❑/– |
| 2.6 | Intended purpose and related definitions | ❑/❑/– |
| 2.7 | Side effects | ❑/❑/– |
| 2.8 | Contraindications | ❑/❑/– |
| 2.9 | Residual risks | ❑/❑/– |
| 2.10 | Interaction with other systems | ❑/❑/– |
| 2.11 | Therapy restrictions | ❑/❑/– |
| 2.12 | Considerations for working on the DWDL and DCDL | ❑/–/– |
| 2.13 | Expected service life | ❑/❑/– |
| 2.14 | Duties of the responsible organization | ❑/❑/– |
| 2.15 | Operator responsibility | ❑/–/– |
| 2.16 | Disclaimer of liability | ❑/–/– |
| 2.17 | Technical documentation | ❑/❑/– |
| 2.18 | Warnings | ❑/–/– |
| 2.19 | SVHC (REACH) | ❑/❑/– |
| 2.20 | Addresses | ❑/❑/– |
| | | |
| **3** | **Structure and views** | |
| 3.1 | Overall view of the distribution systems | ❑/❑/– |
| 3.2 | Overall view of **DWDL** | ❑/❑/– |
| 3.3 | Overall view of **DCDL** | ❑/❑/– |
| | | |
| **4** | **Operation** | |
| 4.1 | Overview of coupling systems on the media supply systems | ❑/❑/– |
| 4.2 | Observe when operating | ❑/❑/– |
| 4.3 | Operating the coupling systems | ❑/–/– |
| 4.4 | Microbiological analysis at the sampling port | ❑/❑/– |
| 4.5 | Microbiological analysis at the dialysis water connection | ❑/❑/– |
| 4.6 | Collecting a sample for chemical analysis | ❑/❑/– |
| | | |
| **5** | **Alarms** | |
| | | |
| **6** | **Cleaning, disinfection** | |
| 6.1 | Generally applicable regulations for cleaning and disinfection | ❑/–/– |
| 6.2 | Precautions | ❑/–/– |
| 6.3 | Surface cleaning, surface disinfection | ❑/❑/– |
| 6.4 | Disinfecting the DWDL | ❑/–/– |
| 6.5 | Cleaning connectors and connection ports | ❑/❑/– |
| 6.6 | Disinfecting connectors and connection ports | ❑/❑/– |
| | | |
| **7** | **Functional description** | |
| 7.1 | Description of procedures | ❑/❑/– |
| | | |
| **8** | **Consumables, accessories, and additional equipment** | |
| 8.1 | Consumables | ❑/❑/– |
| 8.2 | Accessories | ❑/❑/– |

| Description | | Y/N/NA |
|---|---|---|
| 8.3 | Additional equipment | ❑/❑/– |
| | | |
| **9** | **Installation** | |
| 9.1 | Installation requirements | ❑/❑/– |
| 9.2 | Operational qualification | ❑/–/– |
| 9.3 | Removal from service, decommissioning | ❑/❑/– |
| | | |
| **10** | **Transport and storage** | |
| 10.1 | Transport and storage conditions | ❑/❑/– |
| 10.2 | Environmental compatibility/disposal | ❑/❑/– |
| | | |
| **11** | **Technical Safety Checks and maintenance** | |
| 11.1 | Important information for performing the TSC/MA | ❑/❑/– |
| 11.2 | Maintenance procedures | ❑/❑/– |
| | | |
| **12** | **Specifications** | |
| 12.1 | DWDL and DCDL product data | ❑/❑/– |
| 12.2 | Identification label (DWDL and DCDL identification) | ❑/❑/– |
| 12.3 | Transport/storage | ❑/❑/– |
| 12.4 | Materials used | ❑/❑/– |
| | | |
| **13** | **Definitions** | |
| 13.1 | Definitions and terms | ❑/❑/– |
| 13.2 | Abbreviations | ❑/❑/– |
| 13.3 | Symbol | ❑/❑/– |
| 13.4 | Certificates | ❑/❑/– |
| | | |
| **14** | **Options** | |
| | | |
| **15** | **Appendix** | |
| 15.1 | Medical Device Register for the DWDL and DCDL | ❑/❑/– |
| 15.2 | Training Record | ❑/❑/– |
| 15.3 | Quality of dialysis water | ❑/❑/– |
| | | |

Comments:

**Note**

➢ Observe index, important information, and all warnings in the Instructions for Use!

| Trainer | | | |
|---|---|---|---|
| **Date** | | **Name** | **Signature** |
| | | | |
| | | | |
| | | | |
| **Participant** | | | |
| **Date** | **Function** | **Name** | **Signature** |
| | | | |
| | | | |

| Trainer | | | |
|---|---|---|---|
| **Date** | | **Name** | **Signature** |
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# 15.3 Quality of dialysis water

The microbiological and chemical purity of the dialysis fluid prepared in the dialysis clinic is of critical importance for the quality of the patient's treatment. The quality of the dialysis water should comply with local regulations. If no local regulations apply, compliance with the applicable requirements of ISO 23500-3 “Water for haemodialysis and related therapies“ is necessary.

The quality of the dialysis water should be monitored regularly for listed chemical and microbiological contaminants. The monitoring schedule should be based on the results of the system validation. In an existing water treatment system operated under stable conditions, the chemical contaminants in the dialysis water should be monitored at least once every year. This excludes total chlorine which, if present in the feed water, should be monitored at the beginning of each treatment day.

Compliance with requirements for the chemical parameters according to ISO 23500-3 may necessitate additional water pretreatment stages or a change in the yield on the device. The composition of the dialysis water must be checked as part of the performance qualification (PQ), and the water pretreatment must be adjusted as needed.

- **Microbiological quality of fluids for hemodialysis**

| Reference | Medium | Permissible maximum values | |
|---|---|---|---|
| | | Total viable microbial count [CFU/ml] | Endotoxin concentration [EU/ml] |
| ISO 23500-3<br>Water for haemodialysis and related therapies | Dialysis water | < 100 (AL* 50) | < 0.25 (AL* 0,125) |
| ISO 23500-5<br>Quality of dialysis fluid for haemodialysis and related therapies | (Standard) dialysis fluid ** | < 100 (AL* 50) | < 0.5 (AL* 0.25)<br>(Ph.Eur: < 0.25) |

*AL = Action Level. Starting at this concentration, steps must be taken to stop the trend from reaching higher, unacceptable values. This value is typically 50 % of the maximum allowable level.

**Tests for bacterial growth and endotoxins are not required if the dialysis device’s fluid pathway is fitted with a bacteria-retentive and endotoxin-retentive filter that has an appropriate capacity, has been validated by the manufacturer, and is operated and monitored according to the manufacturer's instructions (e.g., DIASAFE plus).

- **Chemical quality of dialysis water**

| ISO 23500-3 | | | | | |
|---|---|---|---|---|---|
| **Contaminants with proven toxicity in dialysis** | **Maximum allowable level [mg/L]** | **Electrolytes** | **Maximum allowable level [mg/L]** | **Trace elements** | **Maximum allowable level [mg/L]** |
| Aluminum | 0.01 | Calcium | 2 | Antimony | 0.006 |
| Lead | 0.005 | Potassium | 8 (*2) | Arsenic | 0.005 |
| Fluoride | 0.2 | Magnesium | 4 (*2) | Barium | 0.1 |
| Total chlorine | 0.1 | Sodium | 70 (*50) | Beryllium | 0.0004 |
| Copper | 0.1 | | | Cadmium | 0.001 |
| Nitrate as (N)* | 2 | | | Chrome | 0.014 |
| Sulfate | 100 (*50) | | | Mercury | 0.0002 (*0.001) |
| Zinc | 0.1 | | | Selenium | 0.09 |
| | | | | Silver | 0.005 |
| | | | | Thallium | 0.002 |

* Values according to the European Pharmacopoeia (Ph. Eur.); applicable regulations must be observed. Other deviations in the Ph.Eur. are: Nitrate: Alarm limit = 2 mg/L nitrate in proportion to the total nitrate molecule $NO_3$. Other harmful substances that are only listed in the Ph.Eur.: Ammonium ($NH_4$): 0.2 mg/L; heavy metals (e.g., Pb): 0.1 mg/L; chloride: 50 mg/L.

For continued compliance with quality standards, checks and disinfections of the dialysis water system must be performed regularly.

**Recommended chemical surveillance**

| | |
|---|---|
| Annual inspection | The dialysis water should be checked for chemical contamination at least once a year. |
| Offline tests | If the feed water or pretreated water is chlorinated and offline tests are used, the total chlorine test should be performed downstream of the activated carbon filter at the beginning of each treatment day, before the first patient treatment. If chloramine is used at a concentration of 1 mg/L or more to disinfect the drinking water supply, the test should be repeated before the start of each patient session. If no patient sessions are scheduled, the test should be carried out approximately every 4 hours during operation. |
| Online tests | For online tests in the water pretreatment system, the chlorine and total hardness parameters, for example, can be monitored using **AquaSENS**. |