What does ultra pure dialysis fluid mean?

**Hemodialysis**

**Clinical Benefits**

- Markedly reduces chronic inflammatory processes (1)
- Lowers the rate of dialysis-induced amyloidosis (2)
- Positively promotes patient’s general nutritional state (3)
- Reduces oxidative stress (4)
- Delays loss of residual renal function (5)
- Reduces cardiovascular morbidity (6)
- Prevents biofilm formation (7)
- Extends life expectancy in long-term dialysis patients (8)

**UPF** – Means maximum reduction of microbiological impurities

- Germ-free (sterile as defined by PhEur: only for batch-wise sterility testing)
- Endotoxin levels < 0.03 IU/ml

**References:**

2. A. Attie, R. Egan, Nephrol Dial Transplant. 2002, 17, 1522-8

**Additional literature:**

2. R. Butbauer et al., ASAIO Journal 1994, 40, 1032-1036
5. R. Nystrand, Nieren- und Hochdruckkrankheiten 1999, 4, 43-48
6. M. Marz-Remus et al., Journal of Hospital Infection 2001, 53, 64-71
9. L. W. Henderson et al., Blood Purif. 1983, 1, 3-8
10. L. W. Henderson et al., Seminars in Dialysis 1993, 6, 26-27

For manufacturing ultra pure dialysis fluid and substitution solution for Online treatment with Dialyse

**The UltraPureFluid System (UPF)**

B. Braun Medizintechnologie GmbH
Schwarzenberger Weg 73-79
34212 Melsungen
Germany
Tel +49(0) 56 61 71-3716
Fax +49(0) 56 61 71-3716
E-Mail: silvia.stoehr@bbraun.com
www.bbraun-dialysis.com
W. 02.04.06/1 Nr. 708 0568A
Microbiological risks in dialysis

Our Solution

Advantages of the UPF system

ULP – for safe and reliable therapy

Inherent to their illness, dialysis patients are susceptible to greater risk factors. In the presence of underlying diseases, microbiological contaminate in dialysis treatment systems* has been shown to induce serious and costly complications.

Treatment with the UltraPureFluid system (UPF) successfully reduces the risks of contaminated dialysis fluid in a significant way. ULP stands for economical, safe and reliable dialysis therapy.

Our UltraPureFluid system (UPF)

A plus for your quality management

UPF is a closed system for manufacturing ultra pure dialysis fluid and infusion solutions for Online therapy that will help you effectively enhance the quality of your dialysis treatments.

Biological mechanisms and clinical consequences

Contaminated dialysis fluid is a risk factor

A dialysis patient is exposed to approx. 20,000 liters of dialysis fluid every year with only a semipermeable membrane separating the dialysis fluid from the blood. Fluid purity is prerequisite to treatment quality.

Biofilm formation is a risk factor

Biofilms are formed by colonies of microorganisms (protein net-works) that can build up on surfaces in bacterially contaminated fluid systems and release toxins, eg. endotoxins, into the dialysis fluid. They are resistant to routine disinfection.

Dialysis Advanced and Dialog® hemodialysis machines

Options for dialysis fluid filters (1 filter or Online filters)

Automated filter integrity testing and check of filter settings before every treatment

Chronic routine disinfection after every treatment

Diacap® Ultra dialysis fluid filters

Hi flow adsorptive polyacrylonitrile membranes; bacterial and endotoxin retention rating ≥ 10^6

Diacap® Ultra dialysis fluid filters with Taul® KF

Hypochlorite, 0.01%, 60°C

Disinfection, cleaning and decontamination with citric acid 50% solution

Outstanding disinfectant and virucidal properties*

Diacap® Ultra dialysis fluid filters with Taul® KF

(Repetitive, 0.01%, 60°C)

Disinfection and cleaning with Taul® KF

Demonstrably extends life expectancy in long-term dialysis patients

Ultra-high microbiological system performance

Gentle, reliable disinfection and cleaning

Easy handling

Automatic test routines maximize safety of overall system

Fig. 1: Risk factors for dialysis patients

Dialysate and peritoneal fluid

Blood cell activation:

- Complement system
- Blood coagulation
- Klein system

Cytokine release

IL1, IL6, TNF

Clinical symptoms

Chronic reactions

Acute reactions

Optimal safe for use after every treatment

Very environmentally compatible, toxicologically harmless and biologically degradable

* Virucidal expertise on parvovirus, Dr. Thränhart, University Lecturer, 2003.

* Water processing system (reverse osmosis, circulation line, concentrates, and dialysis machine)
**Microbiological risks in dialysis**

Even minor bacterial impurities can lead to degradation products that can build up on surfaces in bacterically contaminated fluid systems and release toxins, e.g., endotoxins, into the dialysis fluid. They are resistant to routine disinfection. Biofilms are formed by colonies of microorganisms (protein nets) that can build up on surfaces in bacterially contaminated fluid systems and release toxins, e.g., endotoxins, into the dialysis fluid. They are resistant to routine disinfection.

Biofilm formation is a risk factor

**Biological mechanisms and clinical consequences**

- Contaminated dialysis fluid is a risk factor
- Bioburden in dialysis is a risk factor
- Bioburden in dialysis equipment is a risk factor
- Bioburden in dialysis patients is a risk factor

**Clinical symptoms**

- Infection
- Inflammation
- Anemia
- Increased creatinine
- Hematocrit
- Blood pressure

**Chronic reactions**

- Arthritis
- Arthralgia
- Myalgia
- Fatigue

**Acute reactions**

- Anaphylactic reaction
- Shock
- Hypotension

**Contaminated dialysis fluid**

Dialysis patient is exposed to approx. 20,000 liters of dialysis fluid every year with only a semipermeable membrane separating the dialysis fluid from the blood. Fluid purity is prerequisite to treatment quality.

**Treatment quality**

- UPF is a closed system for manufacturing ultra pure dialysis fluid and infusion solutions for Online therapy that will help you effectively enhance the quality of your dialysis treatments.

**Advantages of the UPF system**

- Significantly improves dialysis treatment quality
- Demonstrably extends life expectancy in long-term dialysis patients
- Great savings potential by preventing complications and interrelated consequential costs
- Ultra-high microbiological system performance
- Gentle, reliable disinfection and cleaning
- Easy handling
- Automatic test routines maximize safety of overall system

**Our Solution**

- A plus for your quality management
- UPF is a closed system for manufacturing ultra pure dialysis fluid and infusion solutions for Online therapy that will help you effectively enhance the quality of your dialysis treatments.

**Our UltraPureFluid system (UPF)**

- **Options for dialysis fluid filters (Online filters)**
- **Automatic filter integrity testing and check of filter efficacy before every treatment**
- **Chemical routine disinfection after every treatment**

**Disinfection, cleaning and decontamination with citric acid 50% solution**

- **Outstanding disinfectant properties**
- **Bactericidal, fungicidal, virucidal properties**

**Disinfection and cleaning with Tiutol® KF**

- **Bactericidal, fungicidal, virucidal properties**
- **Hypochlorite, 4.1%, 60°C**

**Citric acid 50% solution**

- **Demonstrable extends life expectancy**
- **Significantly improves dialysis treatment quality**
- **Ultra-high microbiological system performance**
- **Gentle, reliable disinfection and cleaning**
- **Easy handling**
- **Automatic test routines maximize safety of overall system**

**Our UltraPureFluid system (UPF)**

- **Ultra-high microbiological system performance**
- **Gentle, reliable disinfection and cleaning**
- **Easy handling**
- **Automatic test routines maximize safety of overall system**

**UltraPureFluid system (UPF)**

- **Inherent to their illness, dialysis patients are susceptible to microbiological contamination in dialysis treatment systems**
- **Infection risks for dialysis patients**

**Biological mechanisms and clinical consequences**

- **Cytokine release**
- **Blood coagulation**
- **Complement system**
- **Kinin system**

**Clinical symptoms**

- **Monocytes**
- **Macrophages**
- **Fibroblasts**

**Chronic reactions**

- **Anaphylactic reaction**
- **Shock**
- **Hypotension**

**Acute reactions**

- **Anaphylactic reaction**
- **Shock**
- **Hypotension**

**Biological risks in dialysis**

- **Inherent to their illness, dialysis patients are susceptible to microbiological contamination in dialysis treatment systems**
- **Infection risks for dialysis patients**

**Biological mechanisms and clinical consequences**

- **Cytokine release**
- **Blood coagulation**
- **Complement system**
- **Kinin system**

**Clinical symptoms**

- **Monocytes**
- **Macrophages**
- **Fibroblasts**

**Chronic reactions**

- **Anaphylactic reaction**
- **Shock**
- **Hypotension**

**Acute reactions**

- **Anaphylactic reaction**
- **Shock**
- **Hypotension**

---

*Water processing system (osmosis water), circulation line, concentrates, and dialysis machine associated complications.*

*Virucidal expertise on parvovirus, Dr. Thränhart, University Lecturer, 2003.*

*Disinfection, cleaning and decontamination with citric acid 50% solution.*

**Dialysis fluid filter**

**Diacap® Ultra**

**Dialog Advanced and Dialog+ hemodialysis machines**

**Disinfection and cleaning with Tiutol® KF**

**Citric acid 50% solution**

**UltraPureFluid system (UPF)**

**Metal decoating performance. Reliably removes tough biofilms.**

**Ultra-high microbiological system performance.**

**Gentle, reliable disinfection and cleaning.**

**Easy handling.**

**Automatic test routines maximize safety of overall system.**
Microbiological risks in dialysis

Our Solution

Advantages of the UPF system

- Significantly improves dialysis treatment quality
- Demonstrably extends life expectancy in long-term dialysis patients
- Great savings potential by preventing contamination and interrelated consequential costs
- Ultra-high microbiological system performance
- Gentle, reliable disinfection and cleaning
- Easy handling
- Automatic test routines maximize safety of overall system

UF – for safe and reliable therapy

Inherent to their illness, dialysis patients are susceptible to greater risk factors. In the presence of underlying diseases, microbiological contamination in dialysis treatment systems has been shown to induce serious and costly complications. Treatment with the UltraPureFluid system (UPF) successfully reduces the risks of contaminated dialysis fluid in a significant way. UPF stands for economic, safe and reliable dialysis therapy.

Our UltraPureFluid system (UPF)

- Significantly improves dialysis treatment quality
- Demonstrably extends life expectancy in long-term dialysis patients
- Great savings potential by preventing contamination and interrelated consequential costs
- Ultra-high microbiological system performance
- Gentle, reliable disinfection and cleaning
- Easy handling
- Automatic test routines maximize safety of overall system

Bacterial cell activation:
- Complement system
- Blood coagulation
- Klein system

Cytokine release:
- IL1, IL6, TNF
- IL2, IL18, IL10, TGF-

Clinical symptoms:
- Chronic reactions
- Acute reactions

Disinfection, cleaning and decontamination with citric acid 50% solution
- Outstanding disinfectant and virucidal properties*
- Bactericidal, fungicidal, and virucidal properties*;
- Efficient descaling after every treatment prevents biofilms
- Low consumption and minimal time expenditure; optimally safe for use after every treatment
- Very environmentally compatible, toxicologically harmless and biologically degradable

Dialog Advanced and Dialog+ hemodialysis machines
- Options for dialysis fluid filters (1 filter) or Online filters (2 filters)
- Automatic filter integrity testing and check of filter service life before every treatment
- Chromatographic routine disinfection after every treatment

Diacap® Ultra dialysis fluid filters / Online filters
- Below average filter service life / hours of operation: 100 treatments / approx. 800 h
- Highly adsorptive polysulfone membranes; bacteria and endotoxin removal rating ≥ 10^6

Dialysis fluid from the blood. Fluid purity is prerequisite to treatment quality. Contaminated dialysis fluid is a risk factor. Biofilms are formed by colonies of microorganisms (protein net) that can build up on surfaces in bacterially contaminated fluid systems and release toxins, e.g. endotoxins, into the dialysis fluid. They are resistant to routine disinfection. Treatment with our UltraPureFluid system prevents biofilm formation by eliminating a potential source of microbiological impurities.

Contaminated dialysis fluid is a risk factor

A dialysis patient is exposed to approx. 20,000 liters of dialysis fluid every year with only a semipermeable membrane separating the dialysis fluid from the blood. Fluid purity is prerequisite to treatment quality.

Even minor bacterial impurities can lead to degradation products or toxins. Depending on their size, these toxins are capable of triggering reactions in the patient’s body (Fig. 1). Using ultra pure dialysis fluid with our UltraPureFluid system prevents contamination and its associated complications.

Biofilm formation is a risk factor

Biofilms are formed by colonies of microorganisms (protein net) that can build up on surfaces in bacterially contaminated fluid systems and release toxins, e.g. endotoxins, into the dialysis fluid. They are resistant to routine disinfection.

Treatment with our UltraPureFluid system prevents biofilm formation by eliminating a potential source of microbiological impurities.

Fig. 1: Risk factors for dialysis patients

Biological mechanisms and clinical consequences

Water processing system (osmosis water), circulation line, concentrates, and dialysis machine

Associated complications.

our UltraPureFluid system prevents contamination and its interrelated consequential costs. In the presence of underlying diseases, microbiological contamination in dialysis treatment systems has been shown to induce serious and costly complications. Treatment with the UltraPureFluid system (UPF) successfully reduces the risks of contaminated dialysis fluid in a significant way. UPF stands for economic, safe and reliable dialysis therapy.

UF – for safe and reliable therapy

Inherent to their illness, dialysis patients are susceptible to greater risk factors. In the presence of underlying diseases, microbiological contamination in dialysis treatment systems has been shown to induce serious and costly complications. Treatment with the UltraPureFluid system (UPF) successfully reduces the risks of contaminated dialysis fluid in a significant way. UPF stands for economic, safe and reliable dialysis therapy.

Our Solution

A plus for your quality management

UPF is a closed system for manufacturing ultra pure dialysis fluid and infusion solutions for Online therapy that will help you effectively enhance the quality of your dialysis treatments.

Advantages of the UPF system

- Significantly improves dialysis treatment quality
- Demonstrably extends life expectancy in long-term dialysis patients
- Great savings potential by preventing contamination and interrelated consequential costs
- Ultra-high microbiological system performance
- Gentle, reliable disinfection and cleaning
- Easy handling
- Automatic test routines maximize safety of overall system

Diacap® Ultra dialysis fluid filter

Diacap® Ultra Online filter

Dialog Advanced and Dialog+ hemodialysis machines
What does ultra pure dialysis fluid mean?

**Hemodialysis**

**Clinical Benefits**

- Markedly reduces chronic inflammatory processes (1)
- Lowers the rate of dialysis-induced amyloidosis (2)
- Positively promotes patient’s general nutritional state (3)
- Reduces oxidative stress (4)
- Delays loss of residual renal function (5)
- Reduces cardiovascular morbidity (6)
- Prevents biofilm formation (7)
- Extends life expectancy in long-term dialysis patients (8)

**UPF – Means maximum reduction of microbial impurities**

- Germ-free (sterile as defined by PhEur: only for batch-wise sterility testing)
- Endotoxin levels < 0.03 IU/ml

**References:**


**Additional literature:**

- L.W. Henderson et al., Seminars in Dialysis 1993, 6, 26-27.

**The UltraPureFluid System (UPF)**

For manufacturing ultra pure dialysis fluid and substitution solution for online treatment with Dialog
What does ultra pure dialysis fluid mean?

**Hemodialysis**

**Clinical Benefits**

- Markedly reduces chronic inflammatory processes (1)
- Lowers the rate of dialysis-induced amyloidosis (2)
- Positively promotes patient's general nutritional state (3)
- Reduces oxidative stress (4)
- Delays loss of residual renal function (5)
- Reduces cardiovascular morbidity (6)
- Prevents biofilm formation (7)
- Extends life expectancy in long-term dialysis patients (8)

**UPF – Means maximum reduction of microbiological impurities**

- Germ-free (sterile as defined by Ph Eur: only for batch-wise sterility testing)
- Endotoxin levels < 0.03 IU/ml

**References:**


Additional literature:

- M. Ariët et al., Kidney Int 2001, 59(2), 407-414
- R. Bambauer et al., ASAIO Journal 1994, 40, 102-104
- B. Canaud et al., Blood Purif. 2000, 18(3), 200-13
- B. Canaud et al., Nephrol. Dial. Transplant. 2000, 15, 21-26
- B. Nystrand, Nordisk - Nephrologische Klinik, 1999, 2, 99-100
- E. Moran-Riony, Journal of Hospital Infection 2003, 53, 64-71
- P. J. Knudsen et al., Nephron 1989, 53, 188-193

**The UltraPureFluid System (UPF)**

For manufacturing ultra pure dialysis fluid and substitution solution for Online treatment with Dialog.