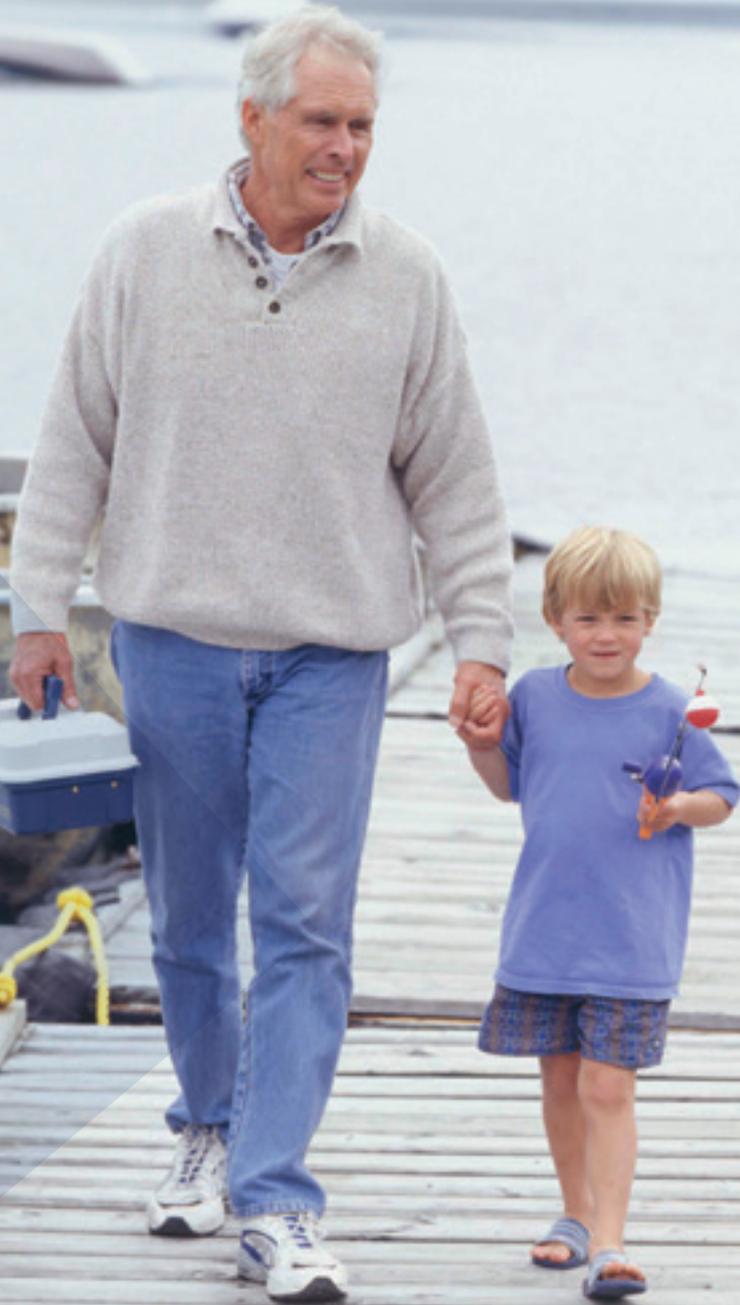


Baxter

Artis Physio
DIALYSIS MONITOR



ARTIS PHYSIO

BECAUSE EVERY PATIENT IS DIFFERENT

ARTIS PHYSIO SYSTEM BECAUSE EVERY PATIENT IS DIFFERENT

The ARTIS PHYSIO dialysis system is inspired by Baxter's passionate commitment to hemodialysis. It provides a range of treatment modalities to meet patient needs through innovative technologies that are designed to simplify everyday operations and enhance user experience.



INDIVIDUALIZED TREATMENT: OVERCOMING HEMODIALYSIS CHALLENGES

Despite many advances in hemodialysis therapy (HD), dialysis-related complications, such as intradialytic hypotension (IDH), dizziness and fatigue are still frequent¹ and can impact the effective delivery of prescription²

Complications associated with end stage renal disease vary between patients, and require different treatment modalities, tailored to individual needs.

The ARTIS PHYSIO system gives you the ability to choose and adapt the therapy to the patient's needs and take advantage of monitoring functions designed to deliver treatment to clinical targets consistently.

ARTIS PHYSIO SYSTEM – DESIGNED FOR EACH AND EVERY PATIENT

INDIVIDUALIZED TREATMENT WITH THE ARTIS PHYSIO DIALYSIS SYSTEM

The ARTIS PHYSIO dialysis system provides necessary treatment modalities and tools to individualize treatments. It combines technological innovation with clinical expertise to offer a range of treatment options such as the BICART SELECT citrate system, the HEMOCONTROL and ULTRACONTROL modalities.



BICART SELECT CITRATE SYSTEM

The acetate-free, citrate-containing dialysis fluid provides benefits for the patient in regard to:

- tolerance to the treatment^{7,9}
- management of acid-base status^{3,9}
- dialysis-induced thrombogenicity^{4,9}



HEMOCONTROL TREATMENT MODALITY

This modality manages fluid removal in a more physiological way, reducing the incidences of intradialytic hypotension (IDH).

- Minimized cardiovascular stress reducing the risk of IDH^{12,14}
- Favourable impact on treatment tolerance and post-dialysis recovery times²⁶



ULTRACONTROL TREATMENT MODALITY

This 'one-button' hemodiafiltration (HDF) modality ensures consistent high convective volumes in HDF post-dilution.^{17,18,28}

- Automated delivery of high volume post dilution with minimal alarms and nurse interventions¹⁷
- Lower risk of all-cause mortality with high-volume HDF¹⁹ in targeted patient groups

THE BICART SELECT CITRATE SYSTEM PROVIDES AN ACETATE-FREE CITRATE-CONTAINING DIALYSIS FLUID

PATIENT COMFORT MATTERS

The level of acetate in standard bicarbonate dialysis fluid is much higher than the normal plasma level and this can cause hemodynamic instability, inflammation, and post-dialysis malaise.⁸ The BICART SELECT citrate system offers a biocompatible replacement of acetic acid to provide citrate-containing dialysis fluid with all the beneficial properties of citrate.

THE BICART SELECT CITRATE SYSTEM IS PART OF THE BICART SELECT SYSTEM

The BICART SELECT system is an effective solution for a tailored prescription of the electrolytes in dialysis fluid. It also offers convenient handling and facilitates the storage of concentrates.

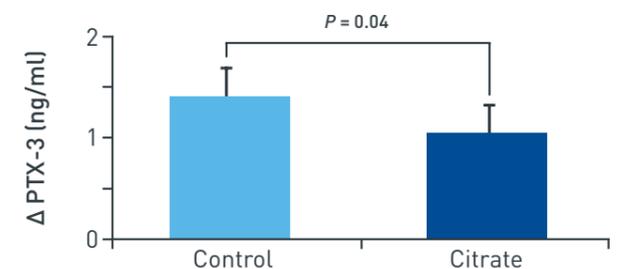
The system includes:

- The BICART cartridge containing dry sodium bicarbonate
- The SELECTCART cartridge containing dry sodium chloride
- The SELECTBAG ONE or the SELECTBAG citrate container providing electrolytes

BICART SELECT CITRATE SYSTEM IMPROVES TOLERANCE TO TREATMENT

In a clinical study using SELECTBAG citrate concentrate, citrate dialysis fluid reduced the intradialytic rise in pentraxin 3 (PTX-3), an inflammatory marker induced by hemodialysis treatment.⁹

Significantly lower intradialytic rise in PTX-3, a marker of inflammation⁹



Reduced intra-dialytic increase in the inflammatory marker pentraxin 3 when using SELECTBAG citrate dialysis fluid compared to control: +1.1 ± 0.3 vs. +1.4 ± 0.3 ng/ml, p=0.04, n=20, Data are shown as means ± SEM, Adapted from Grundstrom⁹



HEMOCONTROL MODALITY CAN REDUCE THE RISK OF INTRADIALYTIC HYPOTENSION¹⁴

The HEMOCONTROL modality: an integrated function for fluid removal adapted to each patient's fluid status.

INTRADIALYTIC HYPOTENSION: A DAILY CONCERN

Episodes of intradialytic hypotension (IDH) can occur in up to 30% of hemodialysis sessions placing a significant burden on your clinic and patient.⁵

Myocardial stunning with regional wall motion abnormalities (RWMA) is common in HD sessions and is associated with higher UF rates, which are also key risk factors for cardiovascular (CV) events and mortality.⁶

HEMOCONTROL MODALITY: CONTROLLING THE REDUCTION OF THE BLOOD VOLUME

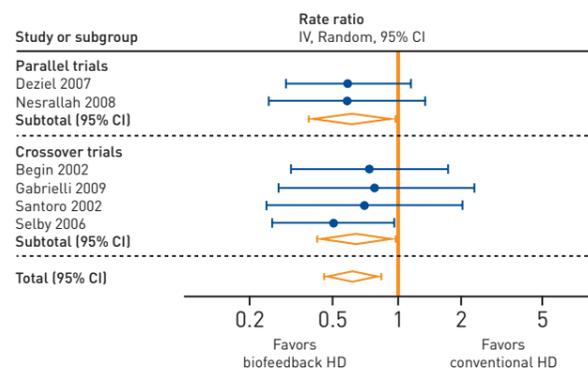
The HEMOCONTROL modality is a biofeedback control of the blood volume; it removes fluid according to the physiological tolerances of the patient. The HEMOCONTROL modality proactively controls the blood volume reduction by regulating ultrafiltration rate and dialysate sodium. This keeps the blood volume in a physiological range and reduces the risk of intradialytic hypotension, compared to conventional HD.^{11,12,14}

The HEMOCONTROL modality has many benefits including:

- Minimized cardiovascular stress reducing the risk of IDH^{12,14}
- Reducing stress on the cardiovascular system.¹²
- Improved treatment tolerability and shorter post-dialysis recovery times²⁶
- Reducing the number of interventions^{13,32}

REDUCE THE RISK OF INTRADIALYTIC HYPOTENSION WITH HEMOCONTROL MODALITY

39% relative risk reduction in the incidence of IDH with the Biofeedback HD versus conventional HD^{14*}
P = 0.005



The Biofeedback HD versus the conventional HD with constant dialysate conductivity and ultrafiltration rate; outcome: IDH, relative treatment effect estimate, HR 0.61; 95% CI, 0.44-0.86; I²=0%, Adapted from Nesrallah¹⁴

SIMPLE AND EFFECTIVE HIGH VOLUME POST-DILUTION HDF WITH THE ULTRACONTROL MODALITY

The ARTIS PHYSIO system offers you the benefits of the ULTRACONTROL modality at the touch of a single button, and makes it possible to deliver high volume post-dilution HDF consistently.

CLINICAL BENEFITS OF HIGH VOLUME POST-DILUTION HDF

The ESHOL clinical trial has demonstrated improved survival and a lower hospitalization rate for patients treated with high blood flow rate when high volume post-dilution HDF can be delivered consistently.¹⁹ Although this sounds simple, the routine implementation requires a high-performing vascular access and poses challenges, such as excessive hemoconcentration and subsequent high-pressure alarms, or even clotting.

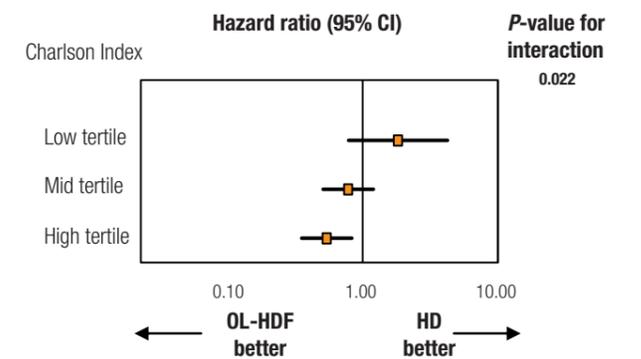
ULTRACONTROL MODALITY: CONTROLLING THE TMP

The ULTRACONTROL modality performs regular and automatic transmembrane pressure (TMP) scans, and makes the necessary adjustments to the TMP value, resulting in high filtration performance of the membrane. This means the session can be completed with no pressure alarms, manual adjustments and nurse interventions are minimized, and the total convective volume is significantly higher, compared with conventional HDF systems.^{16,17,18}

CLINICAL BENEFITS IN RELATION WITH COMORBIDITY INDEX

High volume post-dilution HDF offers excellent blood purification capacity over the full range of solutes, from urea to β_2 -microglobulin, and reduces the risk of all-cause mortality.¹⁹ Sensitivity analysis of the ESHOL study data indicated that the favorable effect of HDF was pronounced in patients with a high comorbidity index.¹⁹

Interaction between the HDF effect on all-cause mortality and patients' Charlson comorbidity index (excl. diabetes).



Adapted from original publication of the ESHOL study results¹⁹
 Maduell F, Moreso F, Pons M, et al. High-efficiency postdilution online hemodiafiltration reduces all-cause mortality in hemodialysis patients. J Am Soc Nephrol. 2013;24(3): 487-497.

⁶ * Results from a meta-analysis of 6 clinical studies [2 randomised, parallel-arm, controlled; 4 randomised, crossover] which reported IDH frequency. Patients were aged >18 years; n ranged from 7 to 60; duration ranged from 4 to 24 weeks. Important sources of bias within studies included lack of blinding of all participants, study personnel and possibly outcome adjudicators and analysts. Data from published randomised studies of biofeedback dialysis lacked sufficient power to evaluate its impact on major outcomes such as survival and hospitalisation rates.¹⁴



RELIABLE AND QUALITY-ASSURED DOSE DELIVERY

BECAUSE EVERY SESSION IS DIFFERENT

Hemodialysis is a complex process and unplanned events may occur, leading to significant variability in the delivery of the prescription. This can reduce the potential clinical benefits for the patient. An approach based on the principles of quality assurance may be helpful to ensure that the therapy is effectively delivered.

QUALITY-ASSURED DIALYSIS

The ARTIS PHYSIO dialysis system provides a unique blend of established and innovative technologies that you can rely on to consistently achieve the treatment goals for your patients, through:

- Automated processes adaptable to various clinical procedures
- Setting of treatment parameters with intuitive user interface and Patient Card
- Early detection of deviation from prescription with the Diascan monitoring system and SmartScan feature
- Individualized sessions with HEMOCONTROL and ULTRACONTROL modalities
- Comprehensive summary of treatment data for traceability and clinical analysis

CONSISTENT DELIVERY OF PRESCRIPTION

The advanced technology and tools integrated in the ARTIS PHYSIO dialysis system aim at providing you with quality-assured dialysis which may reduce variability in treatment delivery and contribute to improved clinical outcomes. With the ARTIS PHYSIO system, the most effective modalities can be used routinely with no additional burden on the clinical staff for reliable prescription delivery.



TREAT EACH AND EVERY PATIENT WITH CONFIDENCE

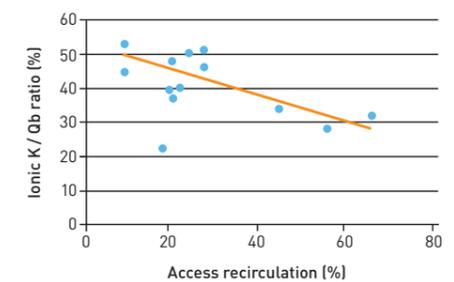
Consistently achieving the dialysis dose can reduce the risk of all-cause mortality and is essential if patients are to receive the benefit of treatment.^{23,24,25}



DELIVERING THE PRESCRIBED DIALYSIS DOSE IN DUE TIME

The Diascan monitoring system is an integrated feature of the ARTIS PHYSIO dialysis system that provides an accurate and real-time measurement of the dialysis efficiency: early indication of the treatment result is provided for optimization of settings if necessary, allowing patients to reach their treatment goals at each treatment.^{20-22,29}

The ratio ionic clearance (Ionic K) / blood flow rate (Qb) is useful to identify recirculation in the vascular access,²⁹ one of the major causes of impaired delivery of dialysis dose



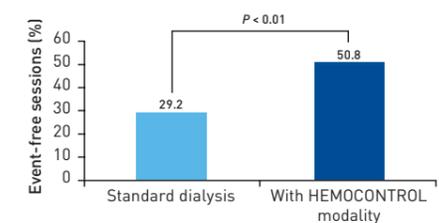
Adapted from Mohan²⁹



PREDICTABLE AND EFFICIENT SESSIONS

The reduction of IDH with the HEMOCONTROL modality significantly increases the number of event-free sessions.²⁷ The prescribed post-dialysis weight is achieved with less complication,^{27,32} making the session more effective and predictable. Patients also benefit from a shorter recovery time,²⁶ facilitating post-treatment procedures.

74% relative increase in event-free sessions with HemoControl modality²⁷



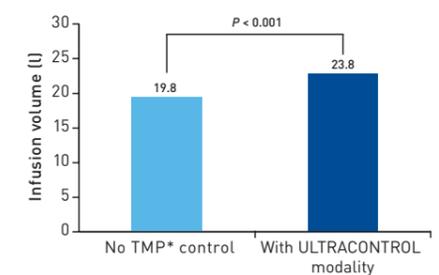
Adapted from Begin²⁷



CONSISTENTLY ACHIEVE HIGH VOLUME POST-DILUTION HDF

The ULTRACONTROL modality is a simple and effective approach to HDF. The complex adjustments required for HDF post-dilution are handled automatically by the ULTRACONTROL modality to ensure high convective volumes, session after session.^{18,17,28} Treatments run with minimal alarms and nurse interventions, compared with systems driving infusion volume without TMP control.¹⁷

+20% relative increase in convective volume¹⁷



*Trans-membrane pressure

Adapted from Panichi¹⁷

THE ARTIS PHYSIO SYSTEM PUTS YOU IN CONTROL OF THE TREATMENT DELIVERY

The modern dialysis clinic is a demanding environment. New technology can make a real difference when it simplifies routine practices and reduces the strain of daily work. The ARTIS PHYSIO system is a product of innovative technology designed with help from human factor engineering and applied research in physical or cognitive ergonomics. Our focus on clinic staff is a top priority. In developing the ARTIS PHYSIO system, Baxter has utilized a user-centered methodology aimed at carefully analyzing every step of the dialysis process to optimize workflow in clinics and reduce physical stress.

TAKE CONTROL OF THE TREATMENT

The touch-screen graphical interface places the user in control with the NavPad controller and intuitive help-on-screen feature.³¹ The five-button NavPad mirrors the normal steps of treatment delivery, allowing you to logically access critical information. You can easily navigate to all working environments, allowing you to manage prescriptions, supervise treatment, access blood and fluid settings, as well as generate treatment reports.



Naturally aligned with workflow



Logically grouped by function

The help-on-screen feature provides step-by-step instructions, guiding the operator through optimal handling when running unusual procedures.



ARTISET BLOOD CIRCUIT: ONE-BUTTON SET-UP

The ARTIS PHYSIO system features an automatic loading process of the ARTISET blood circuit, which also allows one-button auto-priming. Unlike conventional blood circuits, the ARTISET blood circuit requires fewer procedural steps to set up³⁰ and the priming procedure is initiated at the touch of a single button.

The ARTIS PHYSIO system design has grouped all operator actions in one single sequence to prevent waiting times. This means the preparation and priming may be completed with no operator intervention. There is no need to rotate the dialyzer or adjust levels in the chambers.

This automated priming process has the potential to free up time and resources within your clinic without compromising safety.

EVACLEAN: WASTE FREE DRAINING

The priming fluid is automatically drained using the Evaclean function. This integrated device eliminates the handling of draining bag and removes excess waste in your clinic.

THE ARTIS PHYSIO SYSTEM IS READY FOR ANY DIALYSIS ROOM

The ARTIS PHYSIO dialysis system incorporates all of Baxter's dialysis experience and uses proven technology to ensure smooth integration in the dialysis room.

ADAPTABLE TO VARIOUS CLINICAL ENVIRONMENTS

The ARTIS PHYSIO system includes a number of parameters that can be adjusted to meet the many requirements of a dialysis room for flexible clinical integration.

Our highly professional team of experts works with each clinic to ensure that all features of the ARTIS PHYSIO system can be easily integrated into your workflows.

We support this with our strong global service teams that are dedicated to providing you with the tools and support that ensure a successful and short learning period.



THE HYGIENIC CHAIN: 30 YEARS OF PURE WATER FOR YOU AND YOUR PATIENTS

Water quality is a critical factor in dialysis care. Contaminants in the water may affect the efficiency of therapy, performance, and maintenance of equipment. Baxter has designed its entire dialysis offering to protect your patients from the hazards of water contaminants and to help you provide the most beneficial dialysis treatment for your patients.

The ARTIS PHYSIO system allows the user to take advantage of Baxter's experience in maintaining fluid quality through:

- Proven and highly efficient heat disinfection
- Programmable disinfection with full auto-stop and auto-start
- Synchronized process with the Central Water Plant for end-to-end disinfection
- Disinfection history for quality control and traceability



EFFICIENT AND SAFE CARE OF THE FLUID PATH

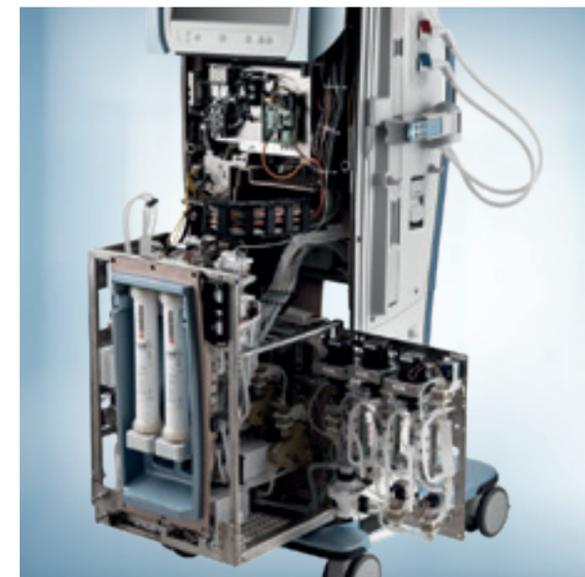
The ARTIS PHYSIO system is designed to operate with the CLEAN-CART cartridge allowing you to run daily cleaning, disinfection, and decalcification; removing the need for chemicals to be present in the dialysis room.

ADVANCED CONNECTIVITY FOR SIMPLIFIED WORKFLOW

Today's clinical environment strives for digitization, improved quality control, and operational efficiency. The ARTIS PHYSIO system is ready to address this challenge.

Connectivity to the ARTIS PHYSIO system allows seamless integration to your IT network. Treatment data can be transferred and stored for traceability and quality assurance.

Data can also be accessed for off-line analysis to better manage clinical outcomes for every patient, individually.



MAINTENANCE AND SUPPORT MADE SIMPLE

The modular design of the ARTIS PHYSIO system allows access to all aspects of the system. The integrated service interface provides you with a range of powerful tools, including presets, calibration, and troubleshooting features. A real-time recording of technical parameters is also stored in an exportable BlackBox for advanced off-line analysis. As part of the Baxter family, you can rely on our customer support to help you perform maintenance procedures and minimize unnecessary downtime.

ARTIS PHYSIO SYSTEM AN ORIGINAL AESTHETIC APPEAL



The modern and innovative design of the ARTIS PHYSIO dialysis system is recognized by healthcare professionals and patients, and may contribute towards making the treatment room a pleasant and relaxed environment.

ARTIS PHYSIO is Baxter's most advanced in-center dialysis system to date. With a range of modalities designed to reduce treatment complications and improve patient comfort, the ARTIS PHYSIO system allows you to consistently achieve your treatment goals.

Easily integrated into the clinic, user-friendly, and efficient, the ARTIS PHYSIO system allows you to deliver individualized treatment. This is crucial as every session is different and every patient is different.



REFERENCES

1. Caplin B, et al. Patients' perspective of haemodialysis-associated symptoms *Nephrol Dial Transplant* 2011; 26(8): 2656-2663
2. Rocco MV, et al. Prevalence of missed treatments and early sign-offs in hemodialysis patients *J Am Soc Nephrol*. 1993 4(5) : 1178-1183
3. Kuragano T, et al. Effects of Acetate-Free Citrate-Containing Dialysate on Metabolic Acidosis, Anemia, and Malnutrition in Hemodialysis Patients Citrate-Containing Dialysate biocompatible *Artif Organs*. 2012; 36(3): 282-290
4. Sands JJ, et al. Effects of Citrate Acid Concentrate on Heparin N Requirements and Hemodialysis Adequacy: A Multicenter, Prospective Noninferiority Trial *Blood Purif* 2012; 33:199-204.
5. Stefánsson B, et al. Intradialytic Hypotension and Risk of Cardiovascular Disease *Clin J Am Soc Nephrol* 2014; 9: 2124-2132
6. Burton J O, et al. Hemodialysis-Induced Cardiac Injury: Determinants and Associated Outcomes *Clin J Am Soc Nephrol* 2009; 4:914-920.
7. Matsuyama K, et al. Acetate-free blood purification can impact improved nutritional status in hemodialysis patients *Artif Organs* 2011; 14(2):112-119.
8. Daimon S, et al. Comparison of Acetate-Free Citrate Hemodialysis and Bicarbonate Hemodialysis Regarding the Effect of Intra-Dialysis Hypotension and Post-Dialysis Malaise *Ther Apher Dial* 2011; 15:460-465.
9. Grundström G, et al. Replacement of acetate with citrate in dialysis fluid: a randomized clinical trial of short term safety and fluid biocompatibility *BMC Nephrol* 2013; 14:216.
10. Basile C, et al. Efficacy and safety of haemodialysis treatment with the Hemocontrol biofeedback system: a prospective medium-term study. *Nephrol Dial Transplant*. 2001; 16(2): 328-334
11. Santoro A, et al. Blood volume controlled hemodialysis in hypotension-prone patients: A randomized, multicenter controlled trial *Kidney Int* 2002; 62:1034-1045.
12. Selby N, et al. Occurrence of Regional Left Ventricular Dysfunction in Patients Undergoing Standard and Biofeedback Dialysis. *Am J Kidney Dis* 2006; 47: 830-841
13. Deziel C, et al. Impact of hemocontrol on hypertension, nursing interventions, and quality of life: A randomised, controlled trial. *Clin J Am Soc Nephrol*. 2013; 2: 661-668
14. Nesrallah GE, et al. Biofeedback dialysis for hypotension and hypervolemia: a systematic review and meta-analysis. *Nephrol Dial Transplant*. 2013; 28:182-191
15. Franssen C, et al. Automatic feedback control of relative blood volume changes during hemodialysis improves blood pressure stability during and after dialysis *Hemodial Int* 2005; 9: 383-392.
16. Teatini U, et al. Evaluation of a New Online Hemodiafiltration Mode with Automated Pressure Control of Convection *Blood Purif* 2011; 31:259-267.
17. Panichi V, et al. Divert to ULTRA: Differences in infused volumes and clearance in two on-line hemodiafiltration treatments *Int J Artif Organs* 2012; 35:435-443.
18. Meroño R, et al. Comparative study between two methods of reinfusion volume control and measurement of the dose of dialysis by ionic dialysance in on-line hemodiafiltration *Diálisis Y Transplante* 2012; 33:37-41.
19. Maduell F, et al. High-Efficiency Postdilution Online Hemodiafiltration Reduces All-Cause Mortality in Hemodialysis Patients *J Am Soc Nephrol* 2013; 24:487-497.
20. Lindsay R, et al. Relationship Between Effective Ionic Dialysance and In Vivo Urea Clearance During Hemodialysis *Am J Kidney Dis* 2001; 38:565-574.
21. McIntyre CW, et al. Assessment of haemodialysis adequacy by ionic dialysance: intra-patient variability of delivered treatment *Nephrol Dial Transplant* 2003; 18:559-562.
22. Mercadal L, et al. Ionic dialysance: Principle and review of its clinical relevance for quantification of hemodialysis efficiency *Hemodial Int* 2005; 9:111-119.
23. Held PJ, et al. The dose of hemodialysis and patient mortality *Kidney Int* 1996; 50:550-556.
24. National Kidney Foundation. Clinical Practice Guidelines *Am J Kidney Dis* 2006; 48 (Suppl.1):S2-S90.
25. Tattersall J et al. EBPG guideline on dialysis strategies *Nephrol Dial Transplant* 2007; 22 (Suppl.22):ii5-ii21.
26. Gil HW, et al. Efficacy of hemocontrol biofeedback system in intradialytic hypotension-prone hemodialysis patients. *J Korean Med Sci*. 2014; 29: 805-810.
27. Begin V, et al. Biofeedback Regulation of Ultrafiltration and Dialysate Conductivity for the Prevention of Hypotension during Hemodialysis *ASAIO J* 2002; 48:312-315.
28. Albalade Ramón M, et al. Clinical application of Ultracontrol®: infusion volume and use with different dialysers *Nefrología* 2011; 31:683-689.
29. Mohan, et al. Effective Ionic Dialysance/Blood Flow Rate Ratio: An Indicator of Access Recirculation in Arteriovenous Fistulae *ASAIO J* 2010; 56(5):427-433.
30. Garzotto F, et al. Priming process of dialyzer: manual versus automatic procedure *ERA-EDTA 2008* [abstract F-PO1573].
31. Ward RA and Ronco C. Improvements in Technology: A Path to Safer and More Effective Hemodialysis *Blood Purif* 2009; 27:6-10.
32. Doria M, et al. The dialysis staff workload and the blood volume tracking system during the hemodialysis sessions of hypotension-prone patients. *Int J Artif Organs*. 2014; 37(4): 292-298

Conforms to requirements in EC Council directive 93/42/EEC, of 14 June 1993, concerning Medical Devices.

For safe and proper use of the device, please refer to the Instructions for Use

CE 0086

Baxter, Artis Physio, ArtiSet, BiCart, BiCart Select, CleanCart, Diascan, HemoControl, NavPad, SelectBag, SelectCart and UltraControl are trademarks of Baxter International Inc. or its affiliates.

EUMP/MG182/15-0007(1) – October 2018

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015
USA
1-800-422-9837