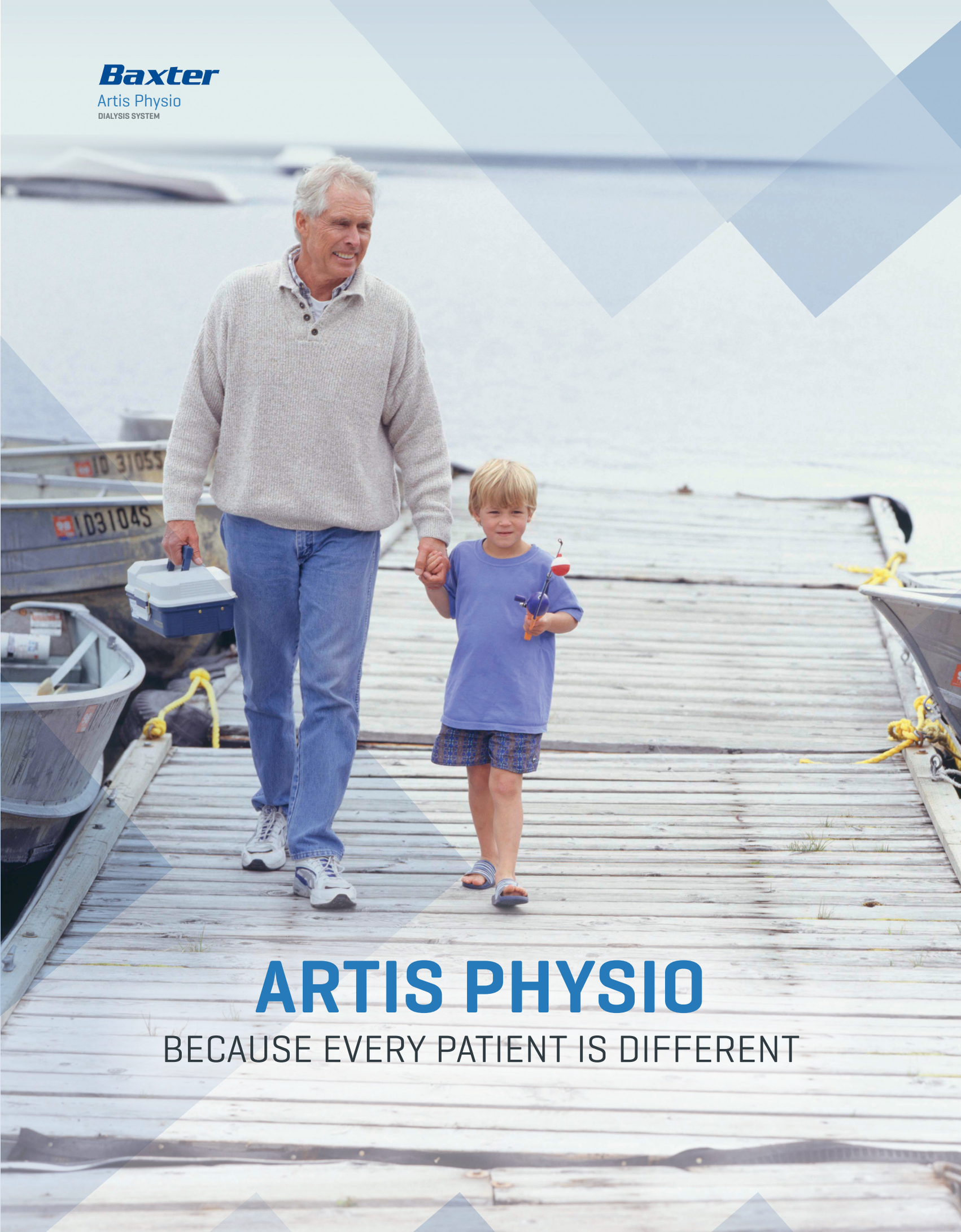
Baxter
Artis Physio
DIALYSIS SYSTEM



ARTIS PHYSIO

BECAUSE EVERY PATIENT IS DIFFERENT

WHEN YOU PURCHASE A HEMODIALYSIS MACHINE YOU BUY A PUMP. WHEN YOU CHOOSE ARTIS PHYSIO YOU ACQUIRE A HOLISTIC OUTCOME.

A TRUSTED PARTNER IN END-TO-END SOLUTIONS
Baxter understands the effort required to run an efficient and effective hemodialysis unit, and we want to support Health Care Professionals every step of the way.

Delivering Support, Worldwide
Baxter Canada has more than 100 HD dedicated employees across the organization: clinical support, sales support, customer support, technical support, medical affairs collaboration with Global digital solutions, Baxter supports dialysis providers in over 60 countries operating more than 100,000 Baxter HD monitors in use worldwide today.

Expanding for and with Health Care Professionals
In the Hemodialysis department at Baxter, we continuously further develop our broad product portfolio – as well as our support and service offerings – in order to help clinics optimize their workflow and streamline the day-to-day operations.

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 frequent[1] and can impact the effective delivery of prescription.[2]

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
TECHNICAL SERVICES

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, designed to simplify everyday operations and enhance user experience.

Baxter is proud of the service we provide to our customers and patients.

- A dedicated team of over 80 service employees are thoroughly trained in all areas of support, and on every product we offer.
- The Baxter team is customer oriented and always seeking collaborations that improve our services.
- We warehouse and manage our own parts and devices inventory with locations across Canada for better, more efficient service for our customers and patients.
- Global knowledge and resources are an integral part of the Baxter Canada service.

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 HEMOCONTROL and ULTRACONTROL modalities, and the BICART SELECT system.

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.[7,9]
- Improved treatment tolerability and shorter post-dialysis recovery times.[21]

ULTRACONTROL TREATMENT MODALITY

This 'one-button' hemodiafiltration (HDF) modality ensures consistent high convective volumes in HDF post-dilution.[12,13,23]

- Automated delivery of high volume post dilution with minimal alarms and nurse interventions.[12]
- Lower risk of all-cause mortality with high-volume HDF[14] in targeted patient groups.

THE BICART SELECT SYSTEM†

Is an efficient solution for a tailored prescription of the electrolytes in dialysis fluid. It also offers convenient handling and facilitates the storage of concentrates.

- Individualizing dialysis fluid composition to the need of the patient is effortless with the BICART SELECT system, where 12 formulations are available.
- Possibility to adjust the sodium or bicarbonate levels while still ensuring that all electrolytes are delivered as prescribed, throughout the treatment.
- Simplified storage with the potential to save up to 60%* space, and no need to lift heavy canisters, helping to minimize back and shoulder strains.
- With the BICART SELECT system weighing approximately 2.92 kg* nurses will lift approximately 7 kg less for each treatment, compared to liquid canisters.

† Products in the BiCart Select System are registered as BiCart, SelectBag One and BiCart Select combi-pak in Canada. BiCart is indicated to be used in a hydrogen carbonate dialysis treatment for patients suffering from acute renal failure, chronic renal failure or acute intoxication with dialysable substances.
SelectBag One is indicated to be used in a bicarbonate dialysis treatment for patients suffering from acute renal failure, chronic renal failure or acute intoxication with dialyzable substances.BiCart Select combi-pak is indicated to be used in a bicarbonate dialysis treatment of patient suffering from acute renal failure, chronic renal failure or acute intoxication with dialysable substances.

* Internal data - please contact your Territory Manager for more information.

HEMOCONTROL MODALITY CAN REDUCE THE RISK OF INTRADIALYTIC HYPOTENSION[9]

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.[3] 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.[4]

HEMOCONTROL MODALITY: CONTROLLING THE REDUCTION OF THE BLOOD VOLUME

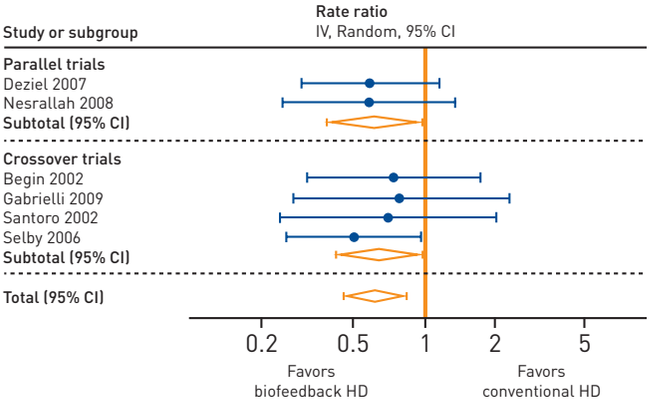
The HEMOCONTROL modality is a biofeedback control of the blood volume; it removes fluid according to the physiological tolerances of the patient. The HEMOCONTROL modality proactively controls the blood volume reduction by regulating ultrafiltration rate and dialysate sodium. This keeps the blood volume in a physiological range and reduces the risk of intradialytic hypotension, compared to conventional HD.[6,7,9]

The HEMOCONTROL modality has many benefits including:

- Minimized cardiovascular stress reducing the risk of IDH.[7,9]
- Reducing stress on the cardiovascular system.[7]
- Improved treatment tolerability and shorter post-dialysis recovery times.[21]
- Reducing the number of interventions.[8,27]

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[9*]
***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 Nesrallah.[9]

* 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.[9]

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.[14] 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.

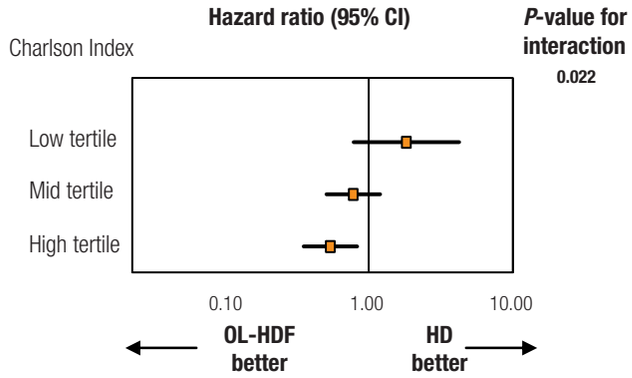
ULTRACONTROL MODALITY: CONTROLLING THE TMP

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.[11,12,13]

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 $ß_2$-microglobulin, and reduces the risk of all-cause mortality.[14] Sensitivity analysis of the ESHOL study data indicated that the favorable effect of HDF was pronounced in patients with a high comorbidity index.[14]

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



Adapted from original publication of the ESHOL study results[14] 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.

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.

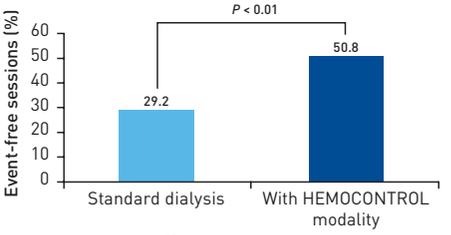
TREAT EACH AND EVERY PATIENT WITH CONFIDENCE

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.[18,19,20]

PREDICTABLE AND EFFICIENT SESSIONS

The reduction of IDH with the HEMOCONTROL modality significantly increases the number of event-free sessions.[22] The prescribed post-dialysis weight is achieved with less complication,[22,27] making the session more effective and predictable. Patients also benefit from a shorter recovery time,[21] facilitating post-treatment procedures.

74% relative increase in event-free sessions with HemoControl modality[22]

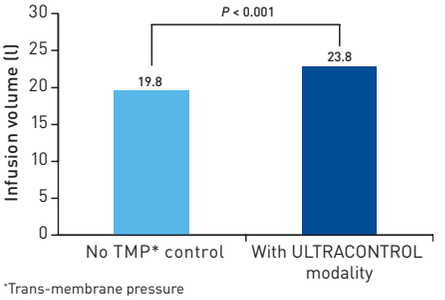


Adapted from Begin[22]

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.[13,12,23] Treatments run with minimal alarms and nurse interventions, compared with systems driving infusion volume without TMP control.[12]

+20% relative increase in convective volume[12]



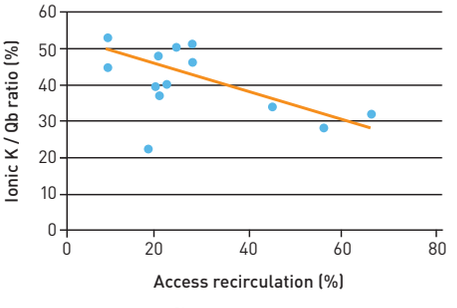
*Trans-membrane pressure

Adapted from Panichi[12]

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.[15-17,24]

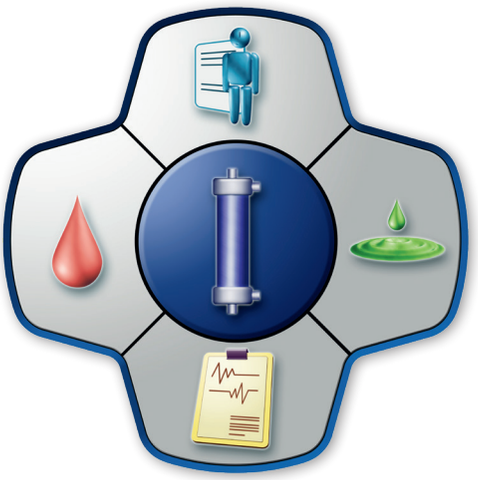
The ratio ionic clearance (Ionic K) / blood flow rate (Qb) is useful to identify recirculation in the vascular access,[24] one of the major causes of impaired delivery of dialysis dose



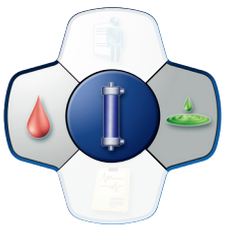
Adapted from Mohan[24]

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.



Naturally aligned with workflow



Logically grouped by function

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.[26] 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.

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 up[25] 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 Baxters 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 Baxters 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 CLEANCART cartridge allowing you to run daily cleaning, disinfection, and decalcification; removing the need for chemicals to be present in the dialysis room.

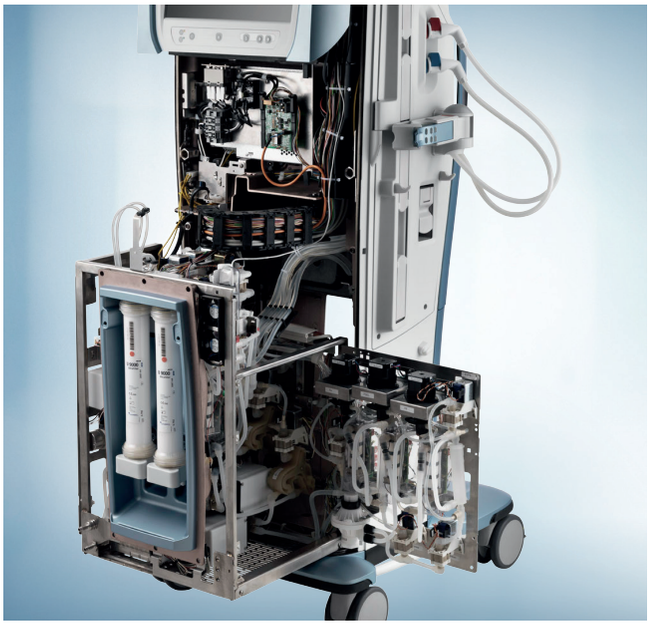
ADVANCED CONNECTIVITY FOR SIMPLIFIED WORKFLOW

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.

The ARTIS PHYSIO system is also complemented by digital health solutions that enable connectivity, integration and interoperability, renal information and workflow management as well as advanced reporting and analytics. These solutions enable improved data management, workflow and operations.



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.

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 container providing electrolytes.

Individualization of the therapy

- Individualizing dialysis fluid composition to the need of the patient is effortless with the BiCart Select system where 12 formulations of electrolytes are available.

Control sodium and bicarbonate independently from the other electrolytes

- Possibility to adjust the sodium or bicarbonate levels while still ensuring that all electrolytes are delivered as prescribed throughout the treatment.

Operational Efficiency

- Simplified storage with the potential to save up to 60%* on space with no need to lift heavy canisters, helping to minimize back and shoulder strains.
- With the BiCart Select system nurses will lift approximately 7 kg less for each treatment, compared to the liquid in canisters, as the weight is approximately only 2.92 kg*.

* Internal data - please contact your Territory Manager for more information.

ARTIS PHYSIO is Baxter's most advanced in-center dialysis system in Canada, 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.

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ARTIS PHYSIO System is an upgraded version of Artis Dialysis System. Intended Use:

The **ARTISDIALYSIS System** is intended to perform intermittent Hemodialysis (HD), Hemofiltration (HF) and Hemodiafiltration (HDF) therapies. The Artis Dialysis System is intended to treat patients with chronic or acute renal failure upon prescription by a physician. The Artis Dialysis System is intended to be used by trained operators in chronic dialysis facilities and Limited Care Centers.

The **ARTISDIALYSIS System** is designed to control and supervise the extracorporeal circuit. To prevent blood coagulation, heparin may be infused through a Heparin delivery system. Moreover, the system produces dialysis, substitution and infusion fluids at a desired temperature, conductivity and pressure within given specifications, and supervises the delivery of fluids.

The **ARTISDIALYSIS System** is designed and validated to support the Gambro BiCart Cartridge and the Gambro BiCart Select system (i.e. the SelectCart cartridge and SelectBag One or SelectBag Citrate container concentrate).

Configuration of the machine for preparation of dialysis fluid using the BiCart Select system is restricted to the countries where mandatory regulatory activities have been completed.

Products in the **BICART SELECT System** are registered as BiCart, SelectBag One and BiCart Select combi-pak in Canada.

BICART:

Indications: To be used in a hydrogen carbonate dialysis treatment for patients suffering from acute renal failure, chronic renal failure or acute intoxication with dialysable substances.

Intended use: The BiCart product is intended for preparation of hemodialysis solutions. The BiCart product is also intended for preparation of hemodiafiltration and hemofiltration substitution fluids on compatible Gambro dialysis systems. The BiCart product must always be used with a suitable acid concentrate.

SELECTBAG One:

Indications: To be used in a bicarbonate dialysis treatment for patients suffering from acute renal failure, chronic renal failure or acute intoxication with dialyzable substances.

Intended use: The **SELECTBAG One** product is intended to be used as an acetic acid based concentrate together with the BiCart Select combi-pak for on-line preparation of haemodialysis, haemodiafiltration or haemofiltration fluids on compabible Gambro dialysis systems.

BICART Select combi-pak:

Indications: To be used in a bicarbonate dialysis treatment of patient suffering from acute renal failure, chronic renal failure or acute intoxication with dialysable substances.

Intended Use: BICART Select combi-pak is intended to be used for on-line preparation of haemodialysis, haemodiafiltration or haemofiltration fluids on compatible Gambro dialysis systems. BiCart Select combi-pak must always be used together with a suitable A-component concentrate.

Consult the following Product Monographs for important information on contraindications, warnings, precautions, adverse reactions, interactions, dosing:

BiCart: https://www.baxter.ca/sites/g/files/ebysai1431/files/2018-11/BiCart_EN.pdf

SELECTBAG ONE: https://www.baxter.ca/sites/g/files/ebysai1431/files/2018-11/SelectBag_One_EN.pdf

BICART SELECT combi-pak: https://www.baxter.ca/sites/g/files/ebysai1431/files/2018-11/BiCart_Select_EN.pdf

The Product Monograph is also available by calling us at 1-800-387-8399.

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

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