



Therapeutic innovation
at the service of the dialysis patient

Physidia, the expert in home dialysis

Physidia is today a major provider of home dialysis. Since its origin, the principle ethos of the company has been innovation with exceptional service by providing comfort, freedom and security to every patient.



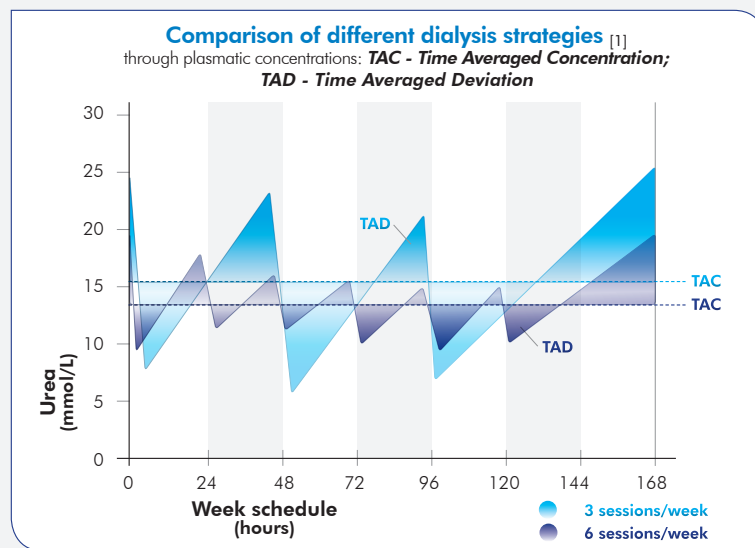
Dialysis innovation providing **comfort and freedom for the patient**

Haemodialysis at home is becoming an increasing popular choice for the renal patient who requires flexibility and freedom to be treated away from the hospital environment. The S³ is a compact and efficient dialysis offering for the patient's home.

The Physidia S³ offers the treatment of renal failure with daily dialysis sessions of 2 to 3 hours 5 to 6 times a week.

A physiological **approach**

Daily hemodialysis is recognized today as the most physiological therapy for the patient experiencing renal failure as this therapy provides outcomes close to natural kidney functioning. [1,2]

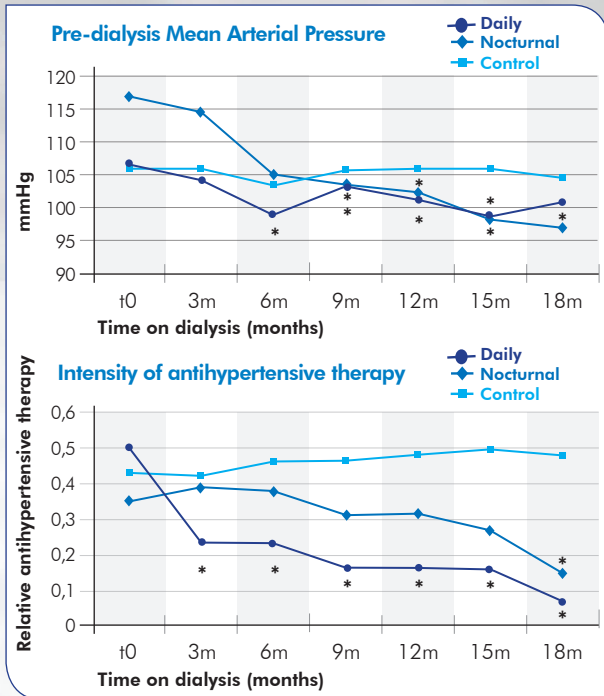


FHN study [2]: 1-year follow-up of 2 cohorts of patients treated 3x / week (53 patients, average 3.6h) and 6x / week (30 patients, average 2.5h): reduction of average plasma concentrations of 15% for 107 uremic toxins (16% to 60% reduction for 32 toxins including urea).

No impact on protein-bound toxins (p Cresol sulfate and indoxyl sulfate).

Increasing the frequency of hemodialysis sessions decreases the mean value and range of change in plasma concentrations of uremic toxins [2]

The main benefits of daily dialysis



"London" study comparing 3 treatment modalities for 11 patients.^[3]

Stable hemodynamic status

Daily hemodialysis maintains the hemodynamic status of the patient with decreased risk of intradialytic hypotension and better regulation of systolic and diastolic hypertension.

Increased frequency of hemodialysis sessions induces a decrease of arterial hypertension.^[3, 4]

Reduction of left ventricular hypertrophy

Reduced hemodynamic variations reduce left ventricular hypertrophy.

Daily dialysis achieves better haemodynamic control by reducing myocardial stress and risk of left ventricular hypertrophy. (measurement by Cardiac Magnetic Resonance Imaging - CMRI, reported in particular by the group «FHN»^[5, 6])

Adapted from [6]	Non adjusted mean variations	Adjusted mean variations (age, diabetes, center)
Left ventricular mass (MVG) g	-13,9 p=0,003	-13,1 p=0,002
MVG g / body surface	-7,1 p=0,005	-6,9 p=0,003
Variation of geometry of left ventricle (CMRI)	-7,5 p=0,02	-7,0 p=0,02

FHN randomised study on 245 patients treated by conventional dialysis 3 by short frequent dialysis during 1 year.^[6]

Optimization of phosphate removal

Mineral metabolic disorders and in particular hyperphosphatemia are independent factors for cardio-vascular mortality.

Frequent hemodialysis improves phosphate removal, maintains a good nutritional level and allows significant reduction of phosphate binders.

In frequent hemodialysis, the FHN group showed complete suppression of chelators in 73% of patients.^[7-9]

	Baseline	6 months	12 months
Conventional hemodialysis (N=51)			
Ca ²⁺ mg/dL	9.0 ± 0.70	8.8 ± 0.55	8.9 ± 0.65
P mg/dL	5.0 ± 1.49	4.9 ± 1.12	5.1 ± 1.14
iPTH pg/mL	717 ± 361	255 ± 182	428 ± 312 ^a
Short daily hemodialysis (N=26)			
Ca ²⁺ mg/dL	8.4 ± 1.26	9.0 ± 0.66	8.9 ± 0.74 ^a
P mg/dL	6.3 ± 2.57	4.6 ± 1.06	4.0 ± 1.19 ^a
iPTH pg/mL	690 ± 596	337 ± 255	312 ± 193 ^a

Prospective controlled study performed on 26 patients treated 6 times a week for 3 hours on a standard dialysis machine.^[8-9]

Improvement of phosphate removal allows significant reduction of phosphate binders and reduces metabolic and cardiovascular complications. ^[7, 8]

An improved **quality of life**

Recent studies show that daily hemodialysis improves significantly the quality of life of patients, and particularly the recovery time between 2 sessions.^[9]

Quality of life parameters	Comparison 6x vs 3x per week Arbitrary scale
Feeling of well being	+6,4 (1,8-11,1) p=0,0071
General health scale	+9,69 (4,68-14,70) p=0,0002
Time to recovery	-84 (-89-(-80)) p<0,0001

Frequent hemodialysis improves the quality of life of the patient.^[9]

Innovation principles of SeCoHD Therapy



SeCoHD (Self-Convective Hemo-Dialysis) therapy is an innovative therapeutic mode of hemodialysis with controlled internal convection.



A controlled **convection technology**

The technology for SeCoHD therapy is via an innovative action of back-filtration and ultrafiltration cycles, due to the control of the difference of transmembrane pressures (TMP) in the dialyser. During the backfiltration, the dialysate is pushed into the blood compartment of the dialyser.

In the next phase, additional ultrafiltration, equivalent to the volume infused in the previous phase, is applied.

It induces a convective transfer of molecules in addition to the diffusive transport of uremic toxins.



The main benefits **of SeCoHD**

SeCoHD therapy has the advantage of leading to the convective purification of uremic toxins autonomously, without the addition of high volume of replacement fluid (> 20l / 4h recommended by the Eshol study).

SeCoHD may be obtained with all type of dialysers, however, this controlled convection is most suited to a high-flux dialyser.

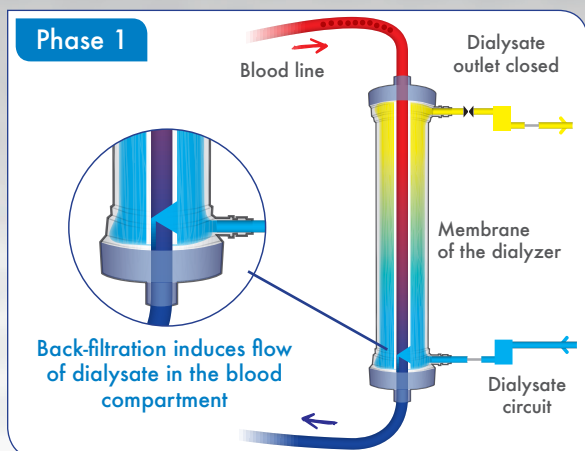
The SeCoHD therapy ensures high levels of convective dialysis without the need for extra substitution fluid and can be performed in the home setting without compromise on treatment.

SeCoHD therapy with S³ monitor

S³ is the only daily hemodialysis monitor performing SeCoHD therapy.

S³ monitor is designed to perform SeCoHD therapy via a succession of back-filtration and ultrafiltration phases throughout the dialysis session.

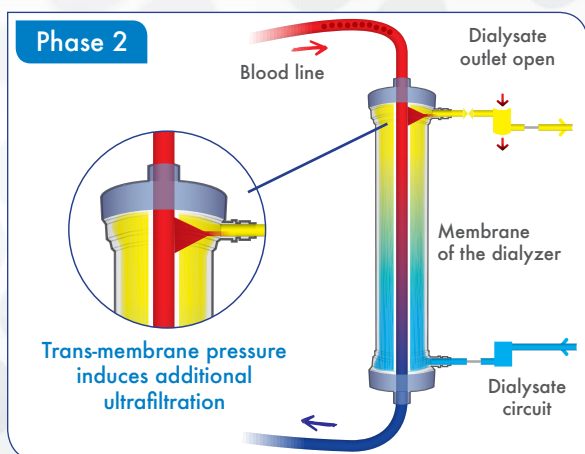
Ultrafiltration volumes are prescribed by the nephrologist or hospital Home dialysis team. The S³ dialysis monitor will operate different cycles to reduce or increase convective volume.



Phase 1: Back-filtration

Back-filtration

Each of the SeCoHD cycles is marked by the activation of a valve that controls the flow of the dialysate leaving the dialyzer. When the valve is closed, back-filtration will occur directing the flow of dialysate through the dialyzer membrane in the blood compartment.



Phase 2: Ultrafiltration and convection

Ultrafiltration

During the next cycle, the valve will open. The trans-membrane pressures will increase the flow creating additional ultrafiltration – thus, the increased convection at this step will allow the diffusion of larger molecules through the membrane. The convective volume with the S³ monitor can vary between 2 and 8 l / dialysis session or up to 48l per week and depends on the prescription of the nephrologist.

Advantages of SeCoHD therapy with S³ monitor

- Improved removal of middle molecules_[10]
- Limiting the clogging of the dialyser membrane
- Increased quality of life due to daily home hemodialysis.



S³ monitor, simplicity via Innovation

Physidia has designed the S³ monitor and its associated consumables for providing ease of use, quality of treatment and comfort during dialysis sessions. The S³ is optimized for daily use at home or incenter.

- S³ monitor performs a hemodialysis therapy with controlled convection via SeCoHD, with ultrafiltration volume prescribed by the nephrologist and monitored automatically by the S³.
- The quality of convective therapy is maintained at home on a daily basis.
- The S³ monitor is simple in its use, secure in its functions and discreet in its appearance.
- The S³ monitor can be used for treatment of patients with fistula or with central catheter vascular access.



➔ S³ monitor

Quality of treatment, freedom and portable



All dialysis data are stored



The patient card,
a guarantee of security



The S³ monitor
in its wheeled bag

> Priority to **safety**

- Medical prescription is saved on the “patient card”. It cannot be modified by the patient.
- Traceability of the different medical devices can be followed
- Dialysis treatment data is saved and /or transferred to the relevant dialysis center at the end of the dialysis session.
- S³ monitor is supplied with emergency battery in order to enable wash back to finish dialysis session safely in case of power failure.
- Thanks to the S³ manual controls, the dialysis session can always be ended safely, even if the tablet is unavailable.

> An interactive tablet **makes the S³ easy to use**

The screen of the monitor is an interactive touch-screen tablet. The user is guided as soon as the monitor is switched on and every procedure is displayed with intuitive instructions on the screen:

- > Preparation of the monitor,
- > Identification of the patient,
- > Verification of the medical prescription,
- > Treatment data of the dialysis session,
- > View of the parameters during the dialysis session and during wash-back.

- The tablet saves all data during the dialysis sessions. This information can be consulted by authorized person.
- Thanks to the tablet, the S³ monitor is a communicating medical device. Data can be exported to a scanned patient record.

> Portability and mobility **for patient freedom**

With its reduced footprint and weighing only 23kg, the S³ monitor can be easily transported, for preserving the freedom and the quality of life of the patient.

Disposables designed for **greater safety and ease of use**

The features of the S³ monitor are based on ready-to-use devices requiring minimal preparation and reducing handling before and after the dialysis session.



The blood circuit on the front of the S³

> An optimized **blood module**

- Integrated ready-to-use blood line grouping arterial-venous line and pressure connectors :
 - Simple and intuitive installation of the blood module
 - Reduces the number of interventions
 - Reduces the extra-corporeal blood volume
 - Reduces infection risk
- The choice of a linear peristaltic pump makes it possible to control the crushing of the pump body and to facilitate the disassembly procedure.



Dialysate cassette automatically supported

> Innovative **dialysate cassette**

- The dialysate cassette is designed with an innovative concept assuring all functions of an in-center dialysis monitor.
- The blood and dialysate circuits are completely independent which minimizes the risk for cross-contamination
- Weight loss is measured with the principle of hydraulic impedences
- The design of the cassette allows performing SeCoHD therapy
- The dialysate cassette is automatically and safely loaded in to position by the S³ monitor.



Sterile and pyrogen-free dialysate bag

> Sterile and pyrogen-free **dialysate bags**

- Use of sterile and pyrogen-free dialysate bags, produced according to pharmaceutical standards, reduces risk of pyrogen transfer through the high-flux dialysers membranes associated with home water treatment systems.
- This provides an assurance to the clinical staff to offer a high flux membranes without risk for patients.
- Bicarbonate and lactate dialysate formulas allow adapting of the medical prescription according to the patient profile.
- A system composed of overlapped consumable trays, communicating with the S³ monitor, validates the reconstitution of the bicarbonate bags before use.



For additional information please contact our
local representative or visit our website
www.physidia.fr

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- [3] Volume control and blood pressure management in patients undergoing quotidian hemodialysis. G. Nesrallah et al, *Am. J. Kidney Dis.* 2003 Jul;42(1 Suppl):13-7.
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- [9] Patients receiving frequent hemodialysis have better health-related quality of life compared to patients receiving conventional hemodialysis, A. X.Garg et al, *Kidney International* (2017) 91, 746–754.
- [10] Engineering perspective on the evolution of push/ pull-based dialysis treatments, K. Lee, *Expert Rev. Med. Devices* 2013; 10(5), 611–620.

The S³ monitor and associated consumables are designed for use in daily hemodialysis for the treatment of chronic renal failure. These Class IIb medical devices are regulated health products that bear, under this regulation, the CE marking in accordance with Directive 93/42 / EEC & 2007/47 / EC. Read the instructions for use provided with the products carefully before use.

Monitor S³, S³.PHYSI.SBAN, S³.PHYSI.DIAL-K1, S³.PHYSI.FLOW-150: certification body CE0459 / LNE GMED.

Manufacturer: PHYSIDIA, 11/13 Bd des Bretonnières - 49124 Saint-Barthélémy.

Blood line S³.PHYSI.LINE : certification body CE0123 / TÜV SÜD.

Manufacturer: F.M. S.p.A Via Farini 65 bis 13043 Cigliano (VC) Italie.

Dialysate bags HMB35/1,5 and HML40/1,5 : certification body - CE0123 / TÜV SÜD.

Manufacturer: HAEMOPHARM BIOFLUIDS s.r.l Via dell'Industria 6, I - 23030 Tovo S. Agata (S.O) Italie.

All products are distributed by: PHYSIDIA, 11/13 Bd des Bretonnières - 49124 Saint-Barthélémy d'Anjou France.

Non-contractual photo.

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S³ is a registered trademark of Physidia SAS

Therapeutic innovation at the service of daily dialysis



The clinical benefits **OF DAILY DIALYSIS**

Cardio-vascular system	
Hypertension [3,4]	↘
Antihypertensive treatment [3]	↘
Left ventricular hypertrophy [5,6]	↘
Phospho-calcic metabolism	
Phosphorus [7,8]	↘
Phosphate binders dose [7]	↘
PTH [7]	↘
Quality of life	
Quality of life (SF36) [9]	↗
Recovery time after dialysis session [9]	↘
General health [9]	↗



The main advantages **OF THE S³ MONITOR**

- Physiological approach
- Quality of treatment with SeCoHD
- Safety and autonomy of the dialysis session
- Freedom and mobility of patients.



Corporate Headquarters: Physidia SAS - 11-13, Bd des Bretonnières - 49124 Saint-Barthélémy d'Anjou - France
Tél. +33(0) 241 731 008

United Kingdom office: Physidia UK Ltd - Unit 69, Atlantic Business Centre, Atlantic Street, Altrincham,
Greater Manchester, WA14 5NQ - United Kingdom - Telephone number: +44(0)161 914 6660

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www.physidia.fr