

bioLogic RR[®] Comfort

Creating dimensions in intelligent blood pressure stabilization



Haemodialysis

Intelligent Dialysis Technology



Creating dimensions in treatment quality

With the Dialog+ dialysis system – available in 3 basic configurations – B. Braun is raising the bar in the field of extracorporeal blood treatment. In Dialog+, intelligent software is perfectly integrated into sophisticated high-grade, hardware-equipped original accessories. As with every one of our products, every purchase is backed by excellent service support and dependable global logistics. The Dialog+ dialysis system represents the foundation of our concept: therapy quality, efficiency and ergonomics.

Why choose bioLogic RR® Comfort?

Over the years, B. Braun has continuously developed and improved its dialysis technology – making it safer for patients, more economical for dialysis centres and more efficient for nurses. Demographic trends indicate that the number of patients dependent on dialysis will continue to grow, thus placing ever increasing demands on haemodialysis procedures.

Dialysis-related complications, such as drops in blood pressure, are an inherent part of the therapeutic process. Causes of hypotensive episodes include losses in intravascular volume, lack of vascular reactivity and other cardiac-related incidents.

These hypotensive episodes require treatments, such as therapeutic interventions and blood pressure stabilising infusions. In the worst case, it may even be necessary to interrupt the dialysis session.

Gentle treatment with bioLogic RR® Comfort

The innovative bioLogic RR® Comfort biofeedback system from B. Braun considerably reduces hypotensive episodes and symptoms during the course of dialysis (Fig. 1). The system is specifically designed for the long-term treatment of chronic haemodialysis patients prone to drops in blood pressure.

bioLogic RR® Comfort is the only biofeedback system that measures the patient's blood pressure directly – a feature which makes the system especially safe and reliable. By automatically regulating the ultrafiltration rate (UFR), bioLogic RR® Comfort prevents the patient's blood pressure from dropping drastically during treatment sessions.

However, the bioLogic RR® Comfort is not limited to just one therapeutic application – in combination with the Dialog+ dialysis machine, the system is compatible with haemodialysis (HD), haemofiltration (HF), haemodiafiltration (HDF) and single-needle (SN) procedures.

State-of-the-art technology with maximum convenience

bioLogic RR® Comfort is the further development of our earlier biofeedback system. During the dialysis session, it automatically measures blood pressure in a closed loop (Fig. 2). The system has been programmed to control the UFR based on precise, scientific medical knowledge and clinical empirical values. In addition to the current blood pressure profile, the system takes into account the blood pressure profiles from previous sessions that are stored in memory.

If a patient's blood pressure moves into a control range defined in the system, a control algorithm is instantly activated. Based on this information, the system autonomously determines if and how the UFR needs to be adapted to the respective treatment situation. Intelligent controls compensate for any conceptual reductions in the UFR during the session. Clinical survey data show that the total ultrafiltration volume is generally achieved within the scheduled treatment time.

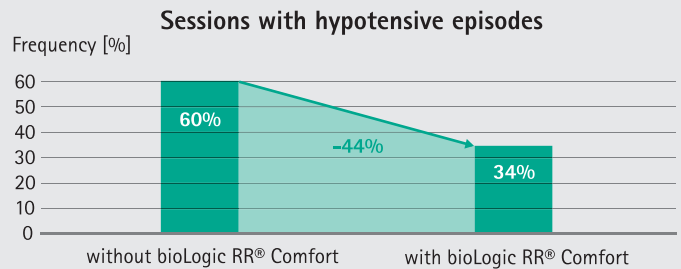


Fig. 1: Reduction in hypotensive episodes

In an 18-week prospective multicenter study on patients prone to hypotensive episodes (60%), the use of bioLogic RR® Comfort lowered the frequency of hypotensive episodes to 34%¹, equivalent to a 44% reduction.

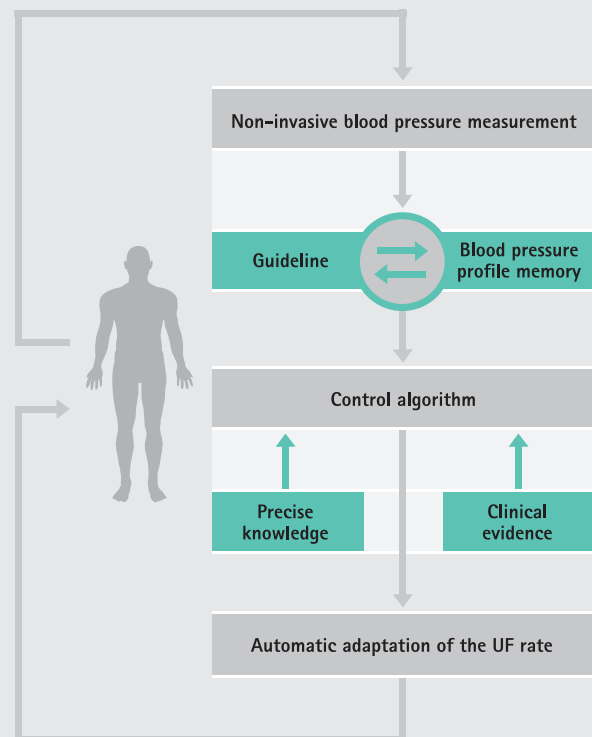


Fig. 2: Control algorithm of bioLogic RR® Comfort

¹ Roehrer O, Schmidt R, Korth S et al.: «bioLogic RR® Comfort reduces hypotensive episodes in patients prone to intradialytic hypotension». 38th Congress of the German Society of Nephrology, Munich, 2007

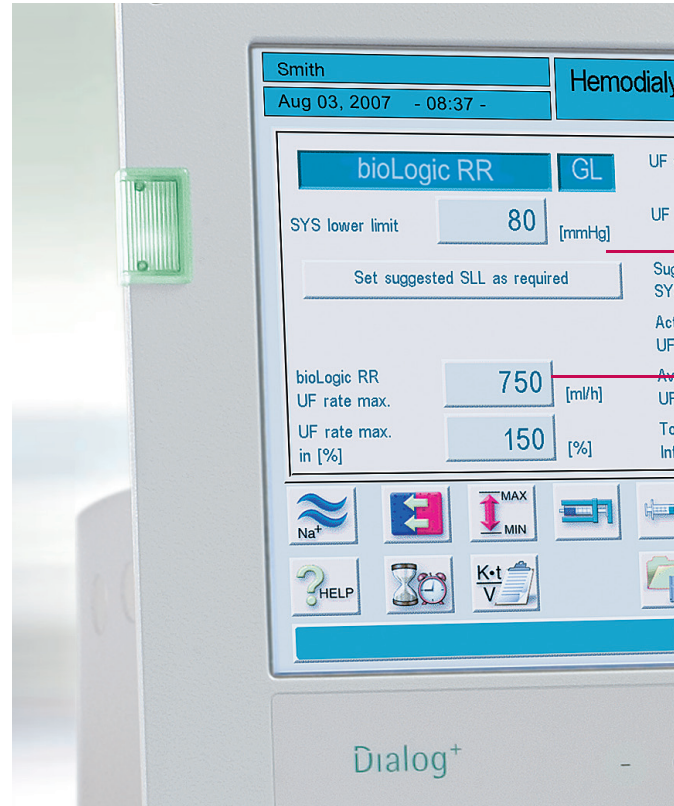
A learning system

Innovative Guideline Technology

Each patient's blood pressure profile follows physiological principles. bioLogic RR® Comfort incorporates this knowledge into the treatment by storing the blood pressure profiles of previous dialysis sessions on the Patient Therapy Card for use in future treatments.

The system performs close-interval blood pressure measurements in the first 45 minutes of the session; it then reads the card's memory to determine the most similar course of therapy stored on it. During the dialysis session, regular measurements ensure that this blood pressure profile is adapted to the current blood pressure of the patient. This generates a "Guideline" that forms the basis for regulating the UFR. Thanks to this technology, the intervals between check measurements towards the end of the session can be extended by up to 30 minutes. Overall, this function can reduce the number of blood pressure measurements by up to 60% compared with the previous system.

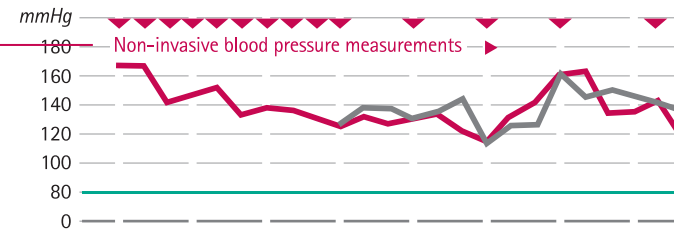
bioLogic RR® Comfort enables early detection of impending hypotensive episodes, thus allowing preventative measures to be undertaken in good time. And the system learns as it goes along – the more data that are stored, the better and more accurate bioLogic RR® Comfort becomes.



Non-invasive blood pressure measurement – RR

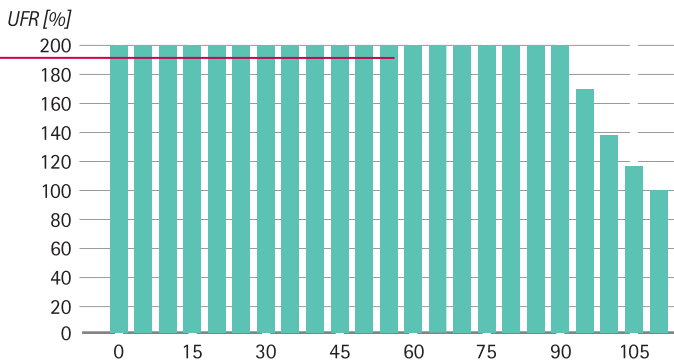
The blood pressure is measured directly on the patient using sphygmomanometry. Automatic blood pressure measurements are performed at 5, 15, 20 and 30-minute intervals, depending on the course of treatment. As few as 18 blood pressure measurements are needed during a complication-free 4-hour dialysis session.

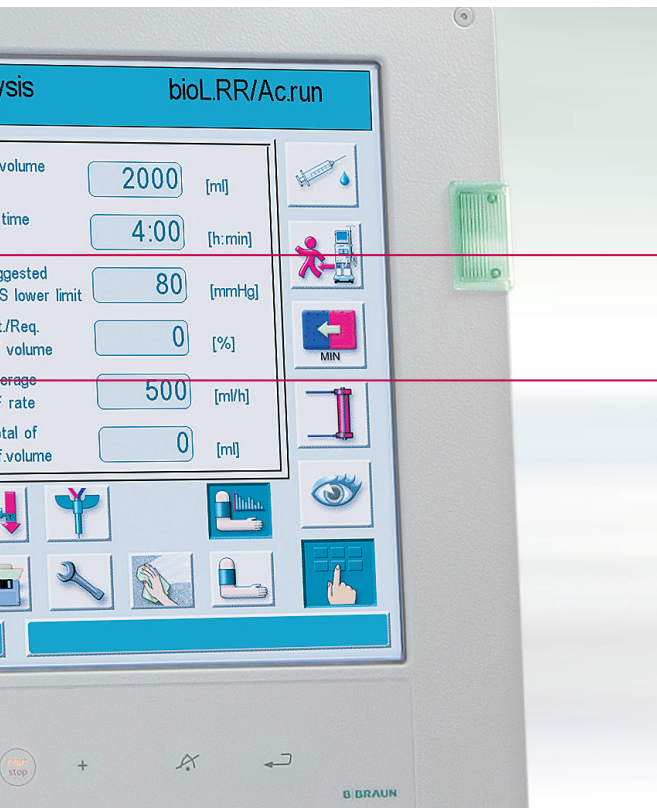
Dialysis-session with bioLogic RR® Comfort



Ultrafiltration rate – UFR

The majority of hypotension-prone dialysis patients tend to experience their blood pressure dropping towards the end of the session. This is why bioLogic RR® Comfort implements ultrafiltration at the start of a dialysis session at up to 200% of the average UFR. As the session proceeds, the system gradually lowers the UFR to 40%. This low UFR means that by the end of the treatment, most patients are able to leave the dialysis centre with stable blood pressure and in a good physical condition.





Setting the Systolic Low Limit (SLL)

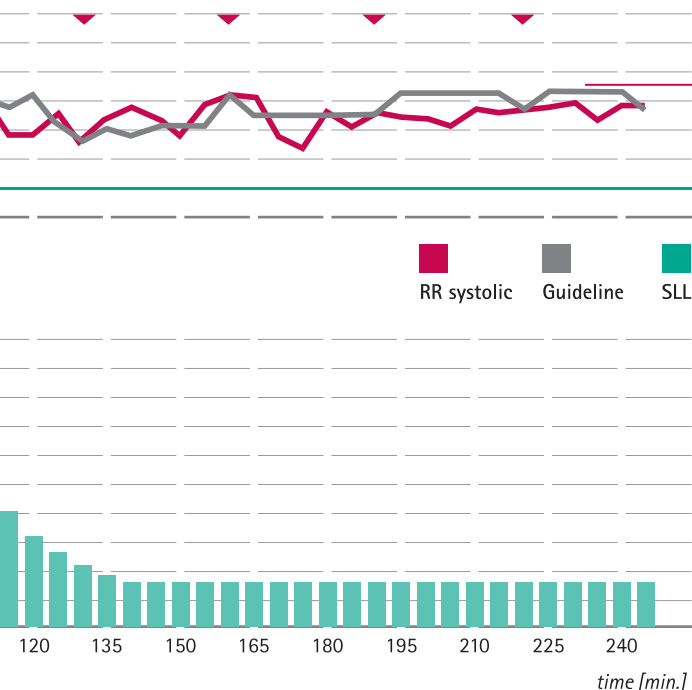
The SLL is the lowest blood pressure permitted by the system. If, in spite of activated control algorithm (trips at 25% above the SLL), the blood pressure falls below this limit, the system instantly adjusts to the lowest possible UF rate.

Based on statistical evaluation of previous sessions, the system calculates the SLL and the nurse usually just needs to confirm the value by tapping the touch screen.

Setting the maximum UFR

The maximum UFR is entered separately for each individual patient. The settings can be entered in milliliters per hour (ml/h) or, alternatively, in percent.

The high UFR achieved at the start of dialysis session are possible due to the low volume extraction at the end of the session. The system is able to exceed the generally applied standard limits, thanks to bioLogic RR® Comfort's integrated Guideline technology.



Guideline - The guiding curve

The Guideline is based on one of the up to 100 blood pressure profiles stored from previous treatments. Once it has been adapted to the conditions of the current dialysis, the new guideline is stored and the oldest curve is deleted.



By storing the data on the Patient Therapy Card, the blood pressure profiles and the most recently used maximum UFR are ready to hand for all future sessions.

Beneficial in every respect

... for users

Not only does bioLogic RR® Comfort help optimise therapy, it also improves many work processes at the dialysis centre.

The economic advantages of bioLogic RR® Comfort are impressive. The reduction in the number of interventions required to treat hypotensive episodes effectively reduces the work load of nursing staff and lowers the costs for blood pressure stabilising saline solutions – and there are no extra costs for special disposables.

The easy handling of the system, with only two key settings required via touch screen, also increases reliability for nursing staff.

The time saved thanks to bioLogic RR® Comfort's quick and easy handling and the reduced time requirements per treatment thanks to Guideline Technology allow more time to be devoted to improving the individual care of patients.

... for patients

bioLogic RR® Comfort significantly reduces the frequency of hypotensive episodes, symptoms and the associated therapeutic interventions (Fig. 3).

Equally, the quality of treatment increases because the system learns over time. This means that it is generally possible to adhere to session times and improve the effectiveness of dialysis.

Furthermore, the significant reduction of blood pressure measurements required compared to the previous system and the special ultrafiltration control considerably enhance the patient's feeling of well-being during and after dialysis.

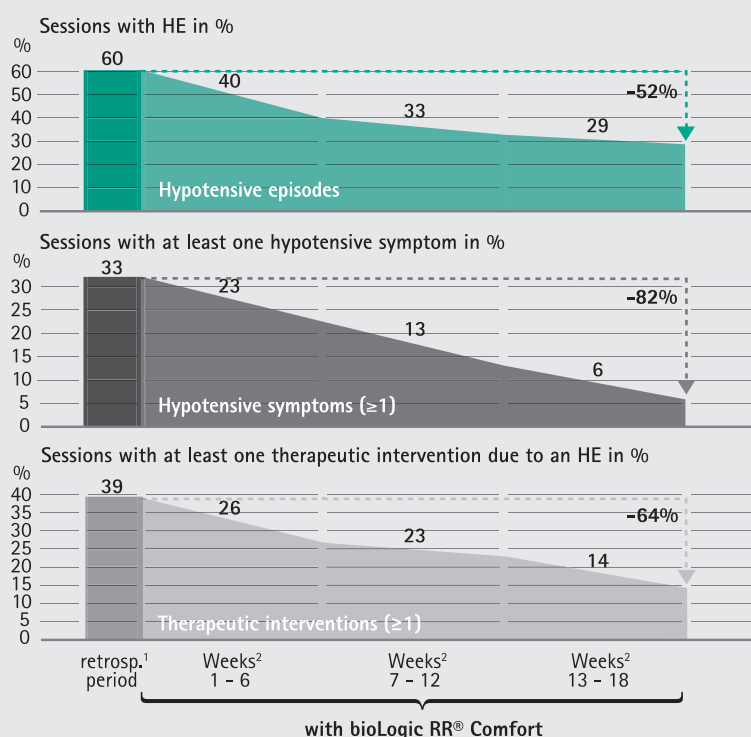
bioLogic RR® Comfort – a learning system³

In order to document the efficiency of bioLogic RR® Comfort, B. Braun conducted an 18-week, prospective, multicenter study on patients prone to hypotensive episodes. Within this period, each patient underwent a total of 54 treatment sessions.

The results of the observational study (Fig. 3) prove that bioLogic RR® Comfort achieves a significant improvement in dialysis treatment after just a few sessions. At the end of the study, the system was already working at high efficiency:

- ▶ 52 % fewer sessions with hypotensive episodes (HE)
- ▶ 82 % fewer sessions with at least one hypotensive symptom
- ▶ 64 % fewer sessions requiring at least one therapeutic intervention due to an HE.

Fig. 3: Results of the observational study



¹ Retrospective period without bioLogic RR® Comfort (7 weeks)

² Means over each period

³ Roeher O, Schmidt R, Korth S et al.:

bioLogic RR® Comfort reduces hypotensive episodes in patients prone to intradialytic hypotension. 38th Congress of the German Society of Nephrology, Munich, 2007

Technical data

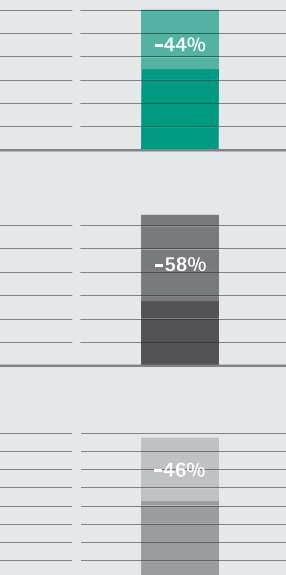


Settings	
Max. UF rate in %	100-200 %
Max. UF rate absolute	0-3000 ml
SLL	65-135 mmHg

Technical data	
Measurement ranges	
Systolic pressure	45-280 mmHg
Diastolic pressure	15-220 mmHg
Mean arterial pressure (MAP)	25-240 mmHg
Accuracy	+/- 3 mmHg or +/- 2 %

Individually adapted alarm limits	
Blood pressure measuring time in an adult with a blood pressure of 120/80 mmHg	approx. 28 sec
Pressure range for the cuff	0-300 mmHg
Default target cuff inflation	200 mmHg
Target cuff inflation pressure/ last systolic pressure	+30 mmHg
Overpressure cut-off	300 mmHg + 10 %

Pressure cuffs are supplied in 3 different sizes



Mean over the entire observational study

References

Roehler O, Schmidt R, Korth S et al.: bioLogic RR® Comfort reduces hypotensive episodes in patients prone to intradialytic hypotension. 38th Congress of the German Society of Nephrology, Munich, 2007.

Mancini E, Mambelli E, Irpina M et al.: Prevention of

dialysis hypotension episodes using fuzzy logic control system. Nephrol Dial Transplant (2007); 22 (5): 1420-1427.

Schmidt R, Roehler O, Korth S et al.: Intradialytic hypotension (IDH): Effective reduction of hypotensive episodes (HE) by blood pressure-guided auto-mated ultrafiltration control (bioLogic RR® Comfort). 40th ASN Meeting, San Francisco, 2007.

Significant reduction in hypotensive episodes

Significant reduction in the number of required BP measurements

Continuous improvement in treatment quality

Reduction in therapeutic interventions

No follow-up costs

Easy handling



Significant reduction in hypotensive episodes

Significant reduction in the number of required BP measurements

Continuous improvement in treatment quality

Reduction in therapeutic interventions

No follow-up costs

Easy handling