Soluție cu bicarbonat (Duosol)

Duosol™ **este o** soluție de dializă / hemofiltrat pe bază de bicarbonat (bicarbonat de sodiu) produsă de B. Braun, destinată tratamentelor de terapie renală de substituție continuă (CRRT)**,** inclusiv pe aparatele din seria OMNI.

Este un lichid steril, gata de utilizat furnizat în pungi cu două camere (double-chamber), conceput pentru preparare ușoară imediat înainte de utilizare.

• Prin ruperea unei cusături simple cele două componente se amestecă, generând soluția finală de utilizat în procedură.

• Ambalajul e color-codificat pe bază de conținutul de potasiu pentru identificare rapidă a formulei.

Utilizare clinică

Indicații principale:

• Soluție de hemofiltrare / dializă continuă (CRRT) în insuficiența renală acută sau alte situații în care este necesară înlocuirea funcției renale continuă.

Scop terapeutic:

• Corectează echilibrul electrolitic și metabolic

• Bicarbonatul asigură un buffer fiziologic pentru corectarea metabolic acidozei asociate insuficienței renale.

Caracteristici principale

✅ *Bicarbonat-buffered* – ajută la menținerea echilibrului acido-bazic în timpul dializei.

✅ *Non-pyrogenic, steril* – reduce riscul de contaminări.

✅ Sistem de pungi cu două camere pentru siguranță și amestec fiabil.
✅ *Conexiuni Luer-lock* – montare sigură la linia de dializă.
✅ Mai multe formule de electroliți (potasiu 0, 2 sau 4 mmol/L, cu sau fără calciu etc.).
✅ Volum tipic: 5000 mL per pungă.

Compoziție tipică (după amestec)

Valorile variază în funcție de formulă, dar un exemplu pentru varianta standard include:
• Na^+ ~ 140 mmol/L
• HCO_3^- ~ 35 mmol/L
• K^+ — 0 / 2 / 4 mmol/L (conform variantei)
• Ca^{2+}, Mg^{2+}, Cl^-, glucoză în concentrații ajustate pentru echilibru electroliți

Note practice
-Alegerea formulei potrivite (ex.: cu sau fără potasiu, cu niveluri diferite de bicarbonat) trebuie făcută de medicul specialist în funcție de starea electrolitică și necesarul pacientului.
Fiind soluție sterilă pentru perfuzie/CRRT, utilizarea e strict în context medical sub supraveghere.

Duosol™
Bicarbonate Dialysate

Acute therapy

Handling Instructions in Four Easy Steps

Open the bag's outer packaging on the side where the hanger holes are located and tear off the outer foil completely.

Unfold the bag and place it on a flat surface.

Squeeze the corners of the small chamber with both hands until the sealing seam between the two chambers starts to open.

Then, press on the large chamber with both hands to ensure the sealing seam is completely open. After mixing, the solution is ready for use.

NOTE:

- Break inner cone above luer lock connection in a forward and backward direction to initiate flow.
- DO NOT USE if container seals or inner cone have been damaged.

NOTE: This informational sheet is not intended to replace the Instructions for Use for the B. Braun Bicarbonate Dialysate solution, or an institution's policies and procedures. Before using the B. Braun Bicarbonate Dialysate, Users should read and be familiar with the complete Instructions for Use and the institution's policies and procedures.

B BRAUN
SHARING EXPERTISE

Renal Therapies Division
Customer Service: 800-848-2066
24/7 Technical Service: 800-621-0445

Duosol™ for Continuous Renal Replacement Therapy

Sterile bicarbonate based dialysate

- Easy to use
- Color-coded labels
- Cost effective

B|BRAUN
SHARING EXPERTISE

Duosol™ for Continuous Renal Replacement Therapy

bicarbonate dialysate in a two-chamber bag

Duosol is a ready-to-use bicarbonate dialysate solution supplied in single use two-chamber bags. It is intended for use with systems used for CRRT.

Color-coded bags with large print

- Break one simple seam for easy and efficient preparation.
- 5L bags minimize bag changes.
- Luer lock connections reduce risk of contamination.
- Color-coded based on Potassium content.
- Available in a variety of formulations to meet your CRRT protocol.

	Na	K	Ca	Mg	Cl	Lactate	HCO_3	Glucose g/L	Est. mOsmL
4551 Bicarbonate 35 Dialysate K0/Ca3 (mEq/L)	140	0	3	1	109	0	35	1	292
4552 Bicarbonate 35 Dialysate K2/Ca3 (mEq/L)	140	2	3	1	111	0	35	1	296
4553 Bicarbonate 25 Dialysate K2/CaO (mEq/L)	136	2	0	1.5	115	0	25	0	278
4554 Bicarbonate 32 Dialysate K2/CaO (mEq/L)	136	2	0	1.5	107.5	0	32	0	278
4555 Bicarbonate 35 Dialysate K4/Ca3 (mEq/L)	140	4	3	1	113	0	35	1	292
4556 Bicarbonate 25 Dialysate K4/CaO (mEq/L)	136	4	0	1.5	117	0	25	0	282

B. Braun Medical is your partner in CRRT. We offer a complete line of products for Continuous Renal Replacement Therapy and Plasma Therapies.

For more information, please contact your B. Braun Renal Therapies Division sales representative, or call Customer Support at **1-800-848-2066.** You can email us at **rtd.us@bbraun.com.**

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www.bbraunusa.com

RTD.025 rev. 2/10 JH 300

B BRAUN
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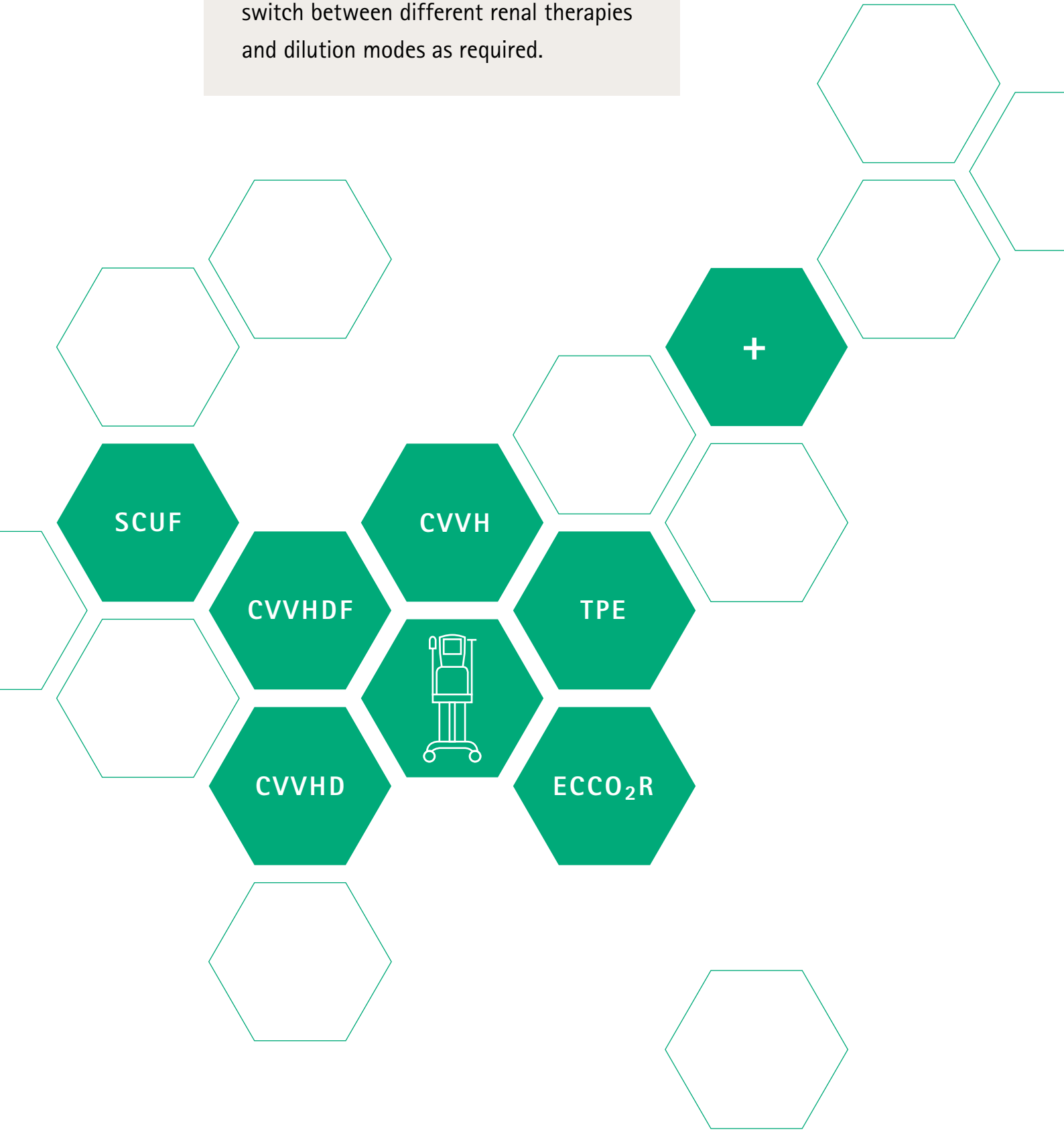
OMNI®

One life means everything

Therapeutic Flexibility

Why settle for less? With OMNI® you can switch between different renal therapies and dilution modes as required.



The OMNI®* acute blood purification system for extracorporeal blood treatments offers multiple Continuous Renal Replacement Therapies (CRRT) and anticoagulation modes. In combination with secondary cartridges or adsorbers, it can serve as a platform for other therapies for extracorporeal multiorgan support of critically ill patients.

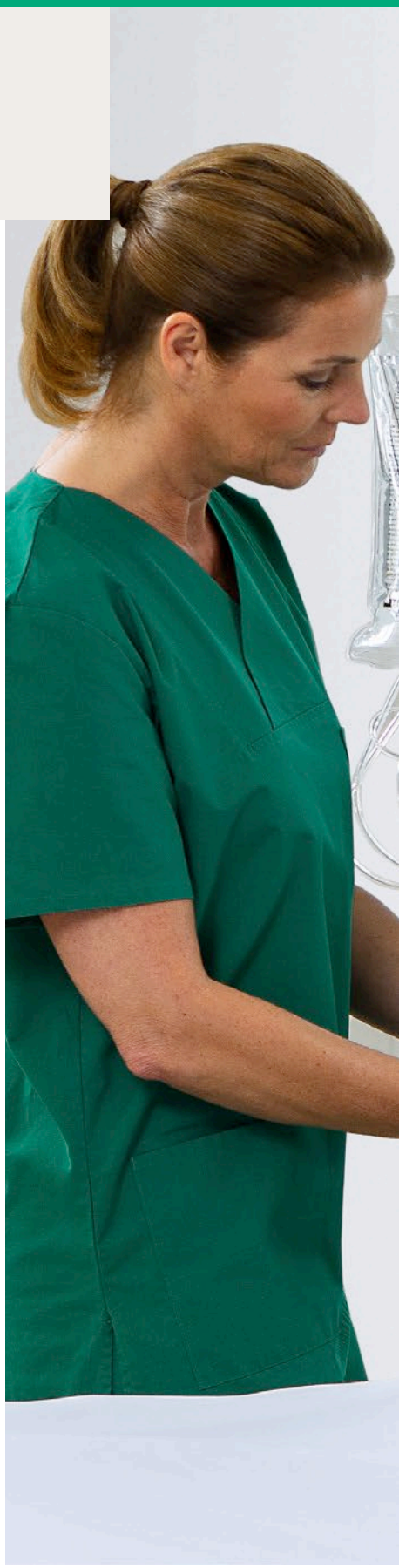
Available treatment modalities:

- CVVH (continuous venovenous hemofiltration)
- CVVHD (continuous venovenous hemodialysis)
- CVVHDF (continuous venovenous hemodia-filtration)
- SCUF (slow continuous ultrafiltration)
- TPE (therapeutic plasma exchange)
- The system can also perform CO_2 removal and adsorbtive therapies in combination with CRRT.

*new SW 1.76 (12/2022)

Treatment Effectiveness

The OMNI® can give you the freedom and the capability to offer your patients the appropriate form of therapy.



As one of the worldwide leaders in the field of extracorporeal blood treatments, B. Braun always strives for a higher level of quality and reliability:

98 % renal dose achievement with less than 5 % down time in CVVHD RCA[1] by compensating certain therapy interruptions

Smart bag movement recognition to reduce unnecessary alarms and therapy interruptions

Patient Care Mode for temporary treatment pauses

An intelligent fluid concept for reduction of alarms and regulation of fluid volumes

1 Schläpfer P, Durovray JD, Plouhinec V, Chiappa C, Bellomo R, Schneider A: A First Evaluation of OMNI®, A New Device for Continuous Renal Replacement Therapy, Blood Purif 2017;43:11–171


B BRAUN
200
Noradrenaline
Propofol
0,5

Handling & Design

OMNI® has been designed with its users in mind. Thanks to the compact design and low weight, it is easy to move the machine inside the ICU. The fully pre-connected Plug & Play OMNIset® can reduce workloads for setup, loading and priming and shorten time required for training.

Automatic priming time of approximately 10 minutes for CRRT and 11 minutes for TPE

Intuitive user interface with step-by-step guidance through the therapy process

Lightweight device (approximately 62 kg) with good mobility and a small footprint allows for easy transport and positioning in the ICU

Barcode scanner ensures the right OMNIset®
for the right therapy

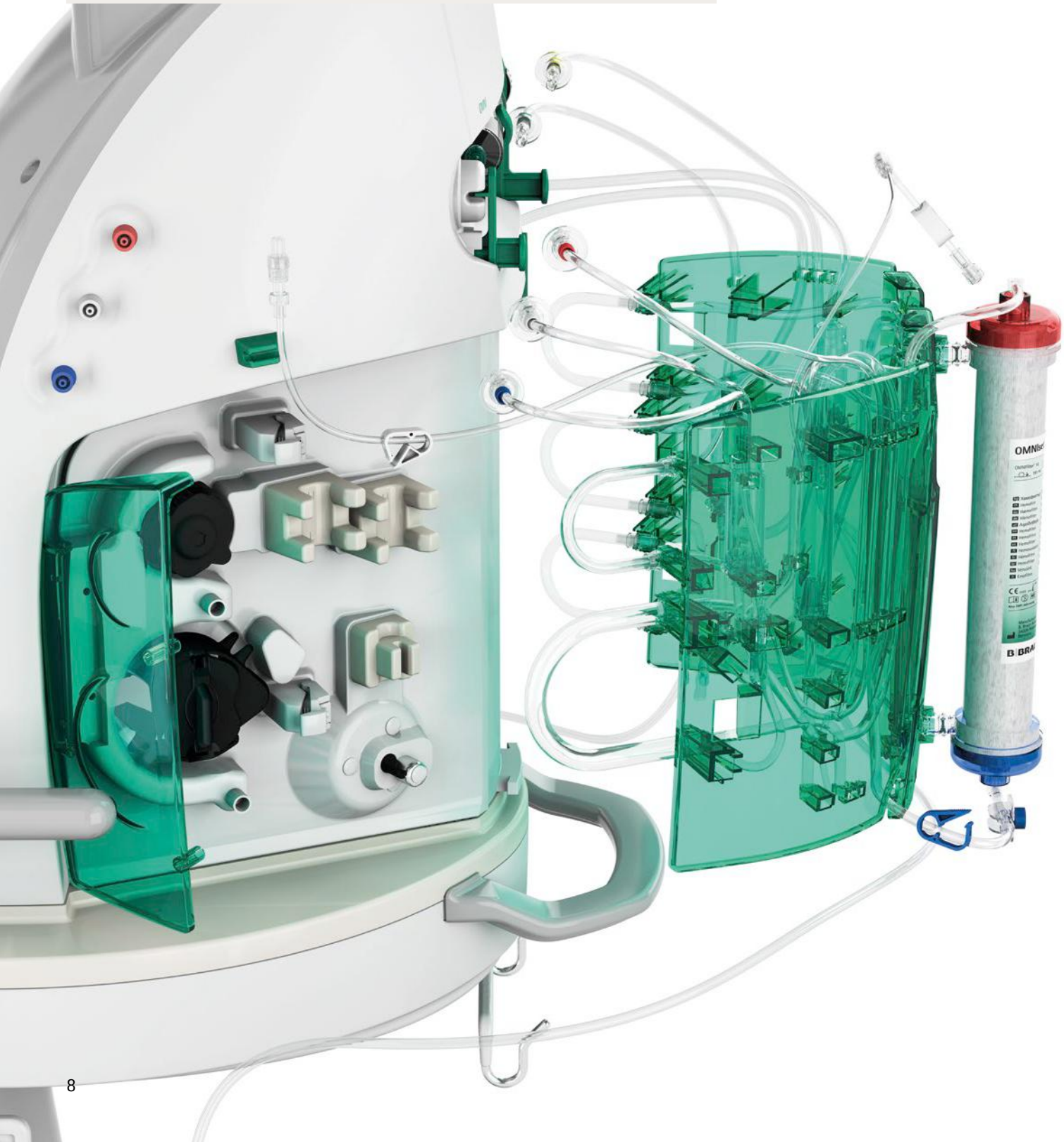
Customizable screensaver visible from a distance of
10 meters

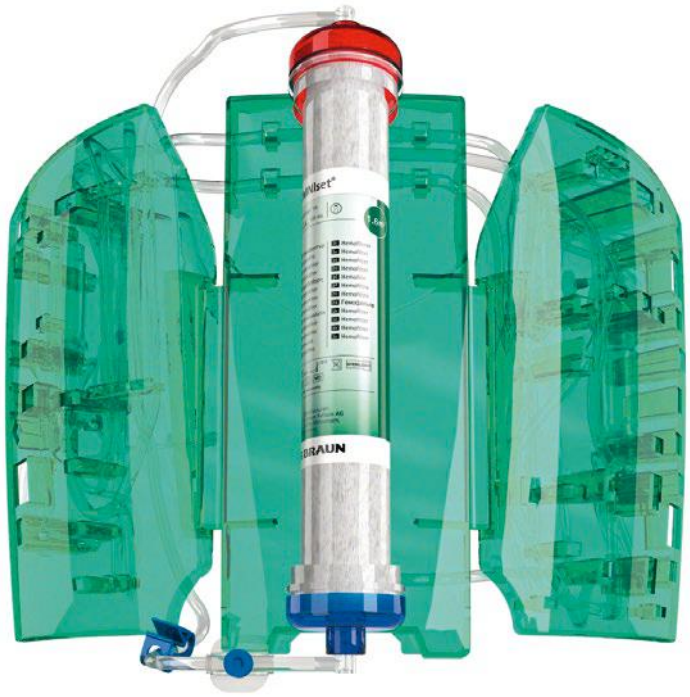
Adjustable screen brightness and alarm volumes to
align with Silent ICU standards

OMNIset®

Fully pre-connected Plug & Play set

OMNIset®* is a pre-connected Plug & Play set designed to provide full flexibility for healthcare professionals to reduce preparation time and workload during the set-up, loading and priming process.





Therapeutic Flexibility

- The fully pre-connected OMNIset® and the easy step-by-step on-screen instructions make setting up the OMNI® simple and fast
- Auto-priming of only 10 minutes for CRRT modalities

Handling & Design

- Fully pre-connected tubing set (including Integrated Warmer bag), color coded lines and connectors, with additional written indication on the Citrate & Calcium lines help to prevent mistakes during set-up

OMNIset®*

Product	Range
OMNIset®	0.8 m^2 – 1.6 m^2
OMNIset® Pro	0.8 m^2 – 1.6 m^2
OMNIset® TPE	0.5 m^2 – 0.7 m^2
OMNIset® L validated for up to 96h	1.6 m^2
OMNIset® Plus	1.6 m^2
OMNIset® ECCO2R	1.6 m^2

OMNIbag®

Product	Size
OMNIbag®	7000 ml Effluent Bag standard
OMNIbag®	7000 ml Effluent Bag with drainage function

*OMNIset® Set Version 3.00 (or higher)

Two solutions – one goal

Driving progress in acute blood purification

Duosol® solution for hemofiltration

A sterile ready-to-use solution for hemofiltration indicated for use in patients with acute renal failure of any cause requiring continuous hemofiltration.

Composition of the ready-to-use solution

Na^+ mmol/l	K^+ mmol/l	Ca^{++} mmol/l	Mg^{++} mmol/l	Cl^- mmol/l	HCO_3^- mmol/l	Glucose mmol/l	Theoret. osmolarity mOsm/l
140	0	1.5	0.5	109	35.0	5.6	292
140	2	1.5	0.5	111	35.0	5.6	296
140	4	1.5	0.5	113	35.0	5.6	300

Packaging type: 1 box contains 2 bags, pallet assembly: 60 boxes

B. Braun Bicarbonate calcium-free solution

A dialysis solution for CVVHD when using citrate anticoagulation.

Composition of the ready-to-use solution

Na^+ mmol/l	K^+ mmol/l	Ca^{++} mmol/l	Mg^{++} mmol/l	Cl^- mmol/l	HCO_3^- mmol/l
136	4	0	0.75	116.5	25
136	2	0	0.75	114.5	25

Packaging type: 1 box contains 2 bags, pallet assembly: 60 boxes

Other formulations and solutions suitable for the use under regional citrate anticoagulation are available upon request.

Please contact your B. Braun respresentative.

The Duosol® solution and bag

Implementing innovation

Our aim in research and development was not only to provide a perfect solution but also a convenient and contemporary double-chamber bag system.

With Duosol® you have a versatile ready-to-use solution in a handy double-chamber bag made of materials fully tested for biocompatibility.

Features at a glance:

- Double-chamber bag
- PVC, Latex and DEHP-free
- Bicarbonate buffered
- Suitable for CRRT
- Simple mixing and usage
- 2-year shelf life

Mandatory Information

Duosol® without Potassium/with 2 mmol/l Potassium/with 4 mmol/l Potassium Hemofiltration Solution

Composition:
Duosol® without Potassium Hemofiltration Solution:

Active ingredients:	Small chamber Electrolyte solution		Large chamber Bicarbonate solution	
	555 ml contain	per 1000 ml	4445 ml contain	per 1000 ml
Sodium chloride	2.34 g	4.21 g	27.47 g	6.18 g
Calcium chloride dihydrate	1.10 g	1.98 g	–	–
Magnesium chloride hexahydrate	0.51 g	0.91 g	–	–
Glucose monohydrate	5.49 g	9.90 g	–	–
corresponding to anhydrous glucose	5.0 g	9.0 g		
Sodium hydrogen carbonate	–	–	15.96 g	3.59 g
Electrolytes:	**[mmol/ chamber]**	**[mmol/l]**	**[mmol/ chamber]**	**[mmol/l]**
Na^+	40.0	72	660	149
Ca^{2+}	7.5	13.5	–	–
Mg^{2+}	2.5	4.5	–	–
Cl^-	75.0	135	470	106
HCO_3^-	–	–	190	42.8
Theoretical osmolarity [mOsm/l]	275		297	

Composition of the ready-to-use hemofiltration solution after mixing: 1000 ml of ready-to-use hemofiltration solution contain: Na^+ 140 mmol/l; Ca^{2+} 1.5 mmol/l; Mg^{2+} 0.5 mmol/l; Cl^- 109 mmol/l; HCO_3^- 35.0 mmol/l; anhydrous glucose 5.6 mmol/l (equivalent to 1.0 g).

Duosol® with 2 mmol/l Potassium Hemofiltration Solution:

Active ingredients:	Small chamber Electrolyte solution		Large chamber Bicarbonate solution	
	555 ml contain	per 1000 ml	4445 ml contain	per 1000 ml
Sodium chloride	2.34 g	4.21 g	27.47 g	6.18 g
Potassium chloride	0.74 g	1.34 g	–	–
Calcium chloride dihydrate	1.10 g	1.98 g	–	–
Magnesium chloride hexahydrate	0.51 g	0.91 g	–	–
Glucose monohydrate	5.49 g	9.90 g	–	–
corresponding to anhydrous glucose	5.0 g	9.0 g		
Sodium hydrogen carbonate	–	–	15.96 g	3.59 g
Electrolytes:	**[mmol/ chamber]**	**[mmol/l]**	**[mmol/ chamber]**	**[mmol/l]**
Na^+	40.0	72	660	149
K^+	10.0	18.0	–	–
Ca^{2+}	7.5	13.5	–	–
Mg^{2+}	2.5	4.5	–	–
Cl^-	85.0	153	470	106
HCO_3^-	–	–	190	42.8
Theoretical osmolarity [mOsm/l]	311		297	

Composition of the ready-to-use hemofiltration solution after mixing: 1000 ml of ready-to-use hemofiltration solution contain: Na^+ 140 mmol/l; **K^+ 2.0 mmol/l**; Ca^{2+} 1.5 mmol/l; Mg^{2+} 0.5 mmol/l; Cl^- 111 mmol/l; HCO_3^- 35.0 mmol/l; anhydrous glucose 5.6 mmol/l (equivalent to 1.0 g).

Duosol® with 4 mmol/l Potassium Hemofiltration Solution:

Active ingredients:	Small chamber Electrolyte solution		Large chamber Bicarbonate solution	
	555 ml contain	per 1000 ml	4445 ml contain	per 1000 ml
Sodium chloride	2.34 g	4.21 g	27.47 g	6.18 g
Potassium chloride	1.49 g	2.68 g	–	–
Calcium chloride dihydrate	1.10 g	1.98 g	–	–
Magnesium chloride hexahydrate	0.51 g	0.91 g	–	–
Glucose monohydrate	5.49 g	9.90 g	–	–
corresponding to anhydrous glucose	5.0 g	9.0 g		
Sodium hydrogen carbonate	–	–	15.96 g	3.59 g
Electrolytes:	**[mmol/ chamber]**	**[mmol/l]**	**[mmol/ chamber]**	**[mmol/l]**
Na^+	40.0	72	660	149
K^+	20.0	36.0	–	–
Ca^{2+}	7.5	13.5	–	–
Mg^{2+}	2.5	4.5	–	–
Cl^-	95.0	171	470	106
HCO_3^-	–	–	190	42.8
Theoretical osmolarity [mOsm/l]	347		297	

Composition of the ready-to-use hemofiltration solution after mixing: 1000 ml of ready-to-use hemofiltration solution contain: Na^+ 140 mmol/l; **K^+ 4.0 mmol/l**; Ca^{2+} 1.5 mmol/l; Mg^{2+} 0.5 mmol/l; Cl^- 113 mmol/l; HCO_3^- 35.0 mmol/l; anhydrous glucose 5.6 mmol/l (equivalent to 1.0 g).

Other ingredients: *Electrolyte solution (small chamber):* Hydrochloric acid 25% (for pH adjustment), Water for Injections; *Bicarbonate solution (large chamber):* Carbon dioxide (for pH adjustment), Water for Injections
Indications: The ready-to-use solution is indicated for use in patients with acute renal failure of any origin who require continuous hemofiltration.
Contraindications
Duosol® without Potassium Hemofiltration Solution/Duosol® with 2 mmol/l Potassium Hemofiltration Solution: *Specific contraindications related to the ready-to-use hemofiltration solution:* Hypokalemia, metabolic alkalosis. *General contraindications related to hemofiltration:* Acute renal failure with pronounced hypercatabolism, where uremic symptoms can no longer be managed by hemofiltration; inadequate blood flow from the vascular access; any condition associated with increased risk of bleeding due to systemic anticoagulation.
Contraindications
Duosol® with 4 mmol/l Potassium Hemofiltration Solution: *Specific contraindications related to the ready-to-use hemofiltration solution:* Hypokalemia, metabolic alkalosis. *General contraindications related to hemofiltration: Acute renal failure with pronounced hypercatabolism, where uremic symptoms can no longer be managed by hemofiltration; inadequate blood flow from the vascular access; any condition associated with increased risk of bleeding due to systemic anticoagulation.*
Adverse reactions: No adverse reactions have been reported that could be directly associated with the bicarbonate-buffered hemofiltration solution. However, the following adverse effects may occur as a consequence of treatment or may be induced by the solution used: Hyperhydration or dehydration, electrolyte imbalance (e.g. hyperkalemia), hypophosphatemia, hyperglycemia, metabolic alkalosis, hypertension, hypotension, nausea, vomiting, muscle cramps.
Warnings: For intravenous use. Refer to the package leaflet. Keep out of reach of children.
Date of information: February 2019. **Pharmacy-only medicine.**
Marketing Authorization Holder: B. Braun Avitum AG, Schwarzenberger Weg 73-79, 34212 Melsungen, Germany

Country-specific marketing authorization for Duosol. Further information on request.

Indications
The ready-to-use solution is indicated for use in patients with acute renal failure of any cause requiring continuous haemofiltration.

Contraindications
Ready-to-use solution dependent contraindications:
- Hypokalaemia (0 and 2 mmol/l potassium)
- Hyperkalaemia (4 mmol/l potassium)
- Metabolic alkalosis

Hemofiltration dependent contra-indications:
- Acute renal failure with marked metabolic processes (hypercatabolism), if the uraemic symptoms cannot be corrected any longer by haemofiltration
- Inadequate blood flow from the vascular access
- All states with elevated hemorrhage risk on account of systemic anticoagulation.

Pregnancy
There are no data from the use of Duosol® in pregnant woman or from animal studies. However, because all the ingredients of the solution for haemofiltration are physiological substances that serve to replace essential plasma components removed by haemofiltration, no risks for the unborn child are to be expected. The use of Duosol® may be considered during pregnancy, if necessary.

Lactation
Because all the ingredients of the solution for haemofiltration are physiological substances that serve to replace essential plasma components removed by haemofiltration, no risks for the child are to be expected. The use of Duosol® may be considered during lactation, if necessary.

Fertility
Because all the ingredients of the solution for haemofiltration are physiological substances that serve to replace essential plasma components removed by haemofiltration, no effects on fertility are to be expected.

Undesirable effects
There have been no reports of adverse events or undesirable effects that might possibly be associated with the bicarbonate-buffered solution for hemofiltration. However, the following adverse reactions could result from the treatment or the solution used:
Hyper- or dehydration, electrolyte disturbances (e.g. hypokalaemia, hyperkalaemia), hypophosphataemia, hyperglycaemia and metabolic alkalosis, nausea, vomiting, muscle cramps, hypertension and hypotension.

Marketing authorization holder:
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Schwarzenberger Weg 73–79
34212 Melsungen, Germany

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Phone +49 5661 71-0 | www.bbraun.com

04-2025