Prolong
Upgrade to Comprehensive PD
P³ – A new approach to Peritoneal Dialysis

P³ is a comprehensive PD programme specifically designed to improve your patients’ quality of life whilst extending their time on PD.

P³ allows you to prescribe individual therapy programmes, monitor patient conditions, and precisely adjust therapy when needed – in an efficient and optimised way.

P³ features three integrated categories:
- **Protect**: unique and easy-to-understand PD systems
- **Preserve**: ultra-low GDP fluids with neutral pH
- **Prolong**: individual state-of-the-art therapies for fluid balance control and guided prescription modelling

**Prolong** helps to improve patient outcomes, quality of life and time on PD through individualised therapy management.

**Prolong is designed to:**
- Aid clinicians in providing individualised therapy options
- Support improved management of fluid status and hypertension
- Assist with routine management of patients through guided prescription modelling
Fluid status – an important survival predictor for PD patients

The treatment of fluid imbalance in PD patients is important because of its role in the development of cardiovascular (CV) disease.\(^1,^2\) CV diseases are the leading cause of death in dialysis patients.

In PD patients, hypervolemia with a subsequent high prevalence of hypertension and left ventricular hypertrophy (LVH) is a major problem.

A principal goal of fluid management is to guide PD patients on a safe path between volume overload and dehydration\(^4,^5\) (see tables below). Without objective means this task can be challenging and time-consuming because:

- Gold standard methods are complex or unavailable
- Ultrafiltration (UF), blood pressure (BP) and body weight are not always causally linked to fluid status.
- Improved fluid status has been correlated with decreased inflammation and improved nutritional status.\(^6\)

### Factors influencing fluid balance in PD patients

<table>
<thead>
<tr>
<th>In</th>
<th>Out</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salt intake</td>
<td>Water intake</td>
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<tr>
<td>Urine</td>
<td>Ultrafiltration</td>
</tr>
</tbody>
</table>

In order to improve fluid balance, all influencing parameters must be taken into account. Simple observation of UF, BP and weight can be misleading and can lead to inadequate therapeutic measures.

### Cardiovascular mortality risk in dialysis patients is higher compared to the general population (GP)\(^3\)

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Dialysis male</th>
<th>Dialysis female</th>
<th>Dialysis black</th>
<th>Dialysis white</th>
<th>GP male</th>
<th>GP female</th>
<th>GP black</th>
<th>GP white</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-34</td>
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<td>35-44</td>
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<td>45-54</td>
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<td>55-64</td>
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<td>65-74</td>
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<td>75-84</td>
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<td>&gt;85</td>
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</tbody>
</table>

Both overhydration and dehydration can have detrimental effects in PD patients.\(^6\)

<table>
<thead>
<tr>
<th>Dehydration</th>
<th>Normohydration</th>
<th>Overhydration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>Normotension</td>
<td>Hypertension</td>
</tr>
<tr>
<td>Loss of RRF</td>
<td>Preservation of RRF / Reduction of CV risk</td>
<td>Loss of RRF / LVH</td>
</tr>
<tr>
<td>Increased mortality</td>
<td>Improved survival</td>
<td>Increased mortality</td>
</tr>
</tbody>
</table>
The BCM-Body Composition Monitor helps to improve therapy with fast, easy and reliable hydration assessment

The **BCM-Body Composition Monitor** is the first device that quantifies the absolute excess fluid amount. It offers simple and reliable assessment of hydration thanks to a unique combination of bioimpedance spectroscopy (BIS) and a specially developed body-composition model. The BCM-Body Composition Monitor determines dry weight and compares it with a reference range allowing clinicians to easily detect abnormalities in hydration. In addition, it determines lean and fat tissue mass.

The **BCM-Body Composition Monitor** provides a reliable decision basis for therapeutic management of PD patients (see table below). At every visit you can assess and monitor your patient’s actual hydration status, allowing you to detect problems early and intervene with corrective measures.

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**The BCM-Body Composition Monitor is as accurate as gold standard reference methods**

\[ * \text{BCM-Body Composition Monitor vs NaBr, } R^2 = 0.81 \]
\[ * \text{Total body water (D}_2\text{O) – intra cellular water (TBK) vs NaBr, } R^2 = 0.75 \]

Reference methods: D\textsubscript{2}O: Deuterium dilution, TBK: Total body potassium, NaBr: Sodium bromide dilution.

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**The BCM-Body Composition Monitor provides a solid decision basis for therapeutic measures in PD**

| Fluid status and blood pressure observed in 150 prevalent PD patients.\textsuperscript{8} |
|-----------------|-----------------|-----------------|-----------------|
| Systolic blood pressure (mmHg) | Dehydration | Overhydration | Hypertension |
| 60 | 80 | 100 | 120 | 140 | 160 | 180 | 200 | 220 | 240 | 260 | 280 | 300 |
| (Over)hydration (L) | -5 | -4 | -3 | -2 | -1 | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

**OH**

Overhydration

**Normo-hydration (dry weight)**

**LTM**

Lean tissue mass

**ATM**

Fat tissue mass

Physiological 3-compartment model used by the BCM-Body Composition Monitor, allowing for direct assessment of patient’s dry weight, hydration status, lean tissue mass (LTM) and fat tissue mass (ATM).
Optimised clinician support for better individual fluid management

Studies confirm that measurements with the BCM-Body Composition Monitor provide essential information that supports clinicians in identifying patients at risk. The ability to detect changes in fluid status and adjust therapy accordingly is likely to have a positive impact on survival.

Clinical advantages of optimised fluid balance:

• Early indication of overhydration or dehydration problems
• Optimised dry weight
• Less anti-hypertensive medication
• Preserved residual renal function
• Reduced cardiovascular risk
• Extended time on PD
• Improved quality of life

The BCM-Body Composition Monitor:

• Determines objective individual dry weight
• Allows for easy patient analysis & management
• Provides results within 2 minutes
• Works regardless of whether the peritoneum is full or empty
• Is non-invasive
• Determines key nutritional parameters (LTM/ATM)
• Traces the clinical development of body composition
**PatientOnLine** is a powerful tool that aids in decision-making by bringing together all facts needed to deliver a high quality PD treatment. It goes beyond a management system for patients’ medical and personal data by offering an integrated solution that is intended to be a complete PD therapy manager.

**PatientOnLine** provides superior follow-up for tracking CAPD and APD patient progress with features such as the adequacy module and prescription modelling. Ultimately it assists you in making the best individualised treatment decisions for each patient.

**Individualised prescriptions with PatientOnLine**

Transport properties of the peritoneal membrane vary from patient to patient as well as in individual patients over time. Assessment of these properties is a basis used to guide therapy. The improved adequacy module offers a comprehensive range of adequacy tests which identify the characteristics of the peritoneum.

The results of the adequacy tests are used by the prescription modelling feature to offer an individualised prescription that fits the patients’ distinct clinical parameters. This eliminates the trial-and-error phase of prescribing, allows you to quickly and more accurately predict the outcome of the treatment, and check patient compliance.

**PatientOnLine:**
- Enables easy creation of individual prescriptions based on adequacy test results and clinical status
- Assists with the creation of prescriptions for CAPD and APD, as well as a mixture of both
- Improves and simplifies patient follow-up by offering an in-depth overview of PD therapy
Protect, Preserve, and Prolong work together to improve survival

At Fresenius Medical Care, we work continuously to improve peritoneal dialysis treatment and therapy. Our work has been validated by numerous studies demonstrating the benefits and advantages of our products, devices and software. The P³ programme allows you to provide your patients with a therapy that Protects, Preserves and Prolongs their time on PD.

To learn more about the P³ categories Protect and Preserve please contact your local sales representative.

The P³ programme is available only from Fresenius Medical Care.
Information balance

balance 1.5% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 2.3% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 4.25% glucose, 1.75 mmol/l calcium, solution for peritoneal dialysis, balance 1.5% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, balance 2.3% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis, balance 4.25% glucose, 1.25 mmol/l calcium, solution for peritoneal dialysis.

These solutions are delivered in a double chamber bag. One chamber contains the alkaline lactate solution, the other chamber contains the acidic glucose-based electrolyte solution. Mixing of both solutions by opening the middle seam between the two chambers results in the neutral ready-to-use solution. Composition: 1 litre of the neutral ready-to-use solution contains: balance 1.5% glucose, 1.75 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 42.5 g, balance 2.3% glucose, 1.75 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 42.5 g, balance 1.5% glucose, 1.25 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.1838 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 22.73 g, balance 4.25% glucose, 1.75 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.2573 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 22.73 g, balance 4.25% glucose, 1.25 mmol/l calcium: sodium chloride 5.640 g, sodium lactate (as sodium lactate solution) 3.925 g, calcium chloride dihydrate 0.1838 g, magnesium chloride hexahydrate 0.1017 g, glucose, anhydrous (as glucose monohydrate) 15 g.

Excipients: Water for injections, hydrochloric acid, sodium hydroxide, sodium hydrogen carbonate. Indications: End-stage (decompensated) chronic renal failure of any origin treated with peritoneal dialysis. Contraindications: Solution related: Solutions with 1.5%/2.3%/4.25% glucose, 1.75 mmol/l calcium: Severe hypokalaemia and severe hypercalcæmia. Solutions with 1.5%/2.3%/4.25% glucose, 1.25 mmol/l calcium: Severe hypokalaemia and severe hypocalcaemia. Solutions with 4.25% glucose: Additionally hypovolaemia and arterial hypotension. Treatment related: Recent abdominal surgery or injury, burns, hernia, inflammatory abdominal skin reaction (dermatitis), inflammatory bowel diseases (Crohn's disease, ulcerative colitis, diverticulitis), peritonitis, non-healing weeping wounds (abdominal fistulae), intra-abdominal tumours, intestinal obstruction (ileus), lung diseases (especially pneumonia), metabolic disorders (lactic acidosis), generalised blood poisoning (sepsis), extreme weight loss (cachexia), particularly when adequate nutrition is impossible, in cases of accumulation of uraemic toxins in the blood (uraemia) the elimination of which can not be managed by peritoneal dialysis, very high levels of fat in the blood (hyperlipidaemia).

Undesirable effects: Infections: Peritonitis (very common); skin exit site and tunnel infections (very common); in very rare cases sepsis. Disorders of the hormone balance for solutions containing 1.25 mmol/l calcium Overactivity of the parathyroid gland with potential disorders of the bone metabolism. Metabolism and nutrition disorders: Increased blood sugar and fat levels; increase in body weight due to the continuous uptake of glucose from the peritoneal dialysis solution. Cardiac and vascular disorders: Frequent pulse; decreased or increased blood pressure. Respiratory disorders: Shortness of breath due to elevation of the diaphragm, shoulder pain. Gastrointestinal disorders: Diarrhoea; constipation; hernia (very common); abdominal distension and sensation of fullness. Renal disorders: Electrolyte disturbances, e.g. decreased potassium levels (very common), increased calcium levels in combination with an increased calcium uptake, e.g. by the administration of calcium containing phosphate binders or decreased calcium levels for solutions containing 1.25 mmol/l calcium. General disorders and administration/catheter site conditions: General malaise; redness, swellings, exudations, crusts and pain at the catheter exit site; dizziness; oedema; disturbances in hydration indicated either by a rapid decrease (dehydration) or increase (overhydration) in body weight. Severe dehydration might occur when using solutions of higher glucose concentration. Peritoneal dialysis procedure related disorders: Cloudy effluent; in- and outflow disturbances of the dialysis solution. Warnings and Precautions: Do not use unless solution is clear and container undamaged. For single use only. Any unused portion of the solution is to be discarded. Do not use before mixing both solutions. The ready-to-use solution must be used within 24 hours after mixing. Do not store below 4°C. Date: December 2010. Fresenius Medical Care Deutschland GmbH, 61346 Bad Homburg v.d.H. Germany.


