Online Clearance Monitoring
Assuring the Desired Dose of Dialysis
Contents

1. Foreword 4

2. Dialysis dose 5
   2.1 Standard methods of determination of the dialysis dose 5
   2.1.1 Urea Reduction Ratio (URR) 5
   2.1.2 Kt/V 5
       Clearance K
       Effective treatment time t
       Urea distribution volume V
   2.1.2.1 Determination of Kt/V using blood samples 7
       Formal urea kinetic modelling
       Single-pool Kt/V (Daugirdas formula)
       Single-pool variable-volume Kt/V
       Double-pool Kt/V (dpKt/V) and its approximation:
           Equilibrated Kt/V (eKt/V)
   2.2 The clinical relevance of dialysis dose 10
   2.3 Recommendations for dialysis dose and the frequency 11
       of measurement of delivered dose

3. Online Clearance Monitoring – OCM® 12
   3.1 The method of OCM® operation 12
   3.2 OCM® in ONLINEplus Haemodiafiltration treatments 17

4. Optimisation of dialysis efficiency 18
   4.1 Blood flow 18
   4.2 Dialysis time 19
   4.3 Dialyser (Membrane surface area, low flux/high flux) 20
   4.4 Dialysate flow rate 20

5. Measurement of plasma sodium with OCM® 22

6. Frequently Asked Questions about OCM® 24

7. References 26
1. Foreword

Online Clearance Monitoring (OCM®) is a standard feature of the Fresenius Medical Care Therapy System 5008 that provides an automatic intradialytic measurement of the effective *in-vivo* urea clearance $K_t$, the total cleared blood water volume $K_t$, the delivered dose of dialysis $K_t/V$ and the plasma sodium concentration of the patient.

With the OCM® it is possible to easily monitor these essential parameters without additional costs during regular ONLINE Haemodiafiltration in either pre- or post-dilution mode, and during haemodialysis treatments.

The OCM® helps physicians and nursing staff to ensure and document on a regular basis that the renal replacement therapy meets the recommended or required quality standards without the need for additional laboratory tests or expenses.

This user brochure provides clinical and technical background information on the OCM®, describes its operation and gives recommendations for the application of the OCM®.
2. Dialysis dose

Similar to the term “dose”, that defines the specific quantity of a medical product or drug required for the treatment of a patient, the dialysis dose can be defined as the quantity of dialysis treatment delivered for a given period of time. In general the dialysis dose is measured by the comparison between the baseline and final concentration of a defined substance in the blood of the patient. The more efficient the dialysis session, the greater the reduction of this given substance is.

In theory, it is possible to determine how efficient any substance which is present in the blood has been removed during dialysis. Even though different methods have been developed to measure the dialysis dose, changes in urea concentration are monitored in order to determine the dialysis dose in standard practice.

2.1 Standard methods of determination of the dialysis dose

2.1.1 Urea Reduction Ratio (URR)

A simple and commonly-used method of determining the dose of dialysis is the calculation of the Urea Reduction Ratio (URR). This involves a direct comparison of pre- and postdialytic urea concentrations and shows the percentage reduction of the urea concentration during dialysis treatment \(^{(1)}\).

\[
URR = 100 \left(1 - \frac{C_{\text{post}}}{C_{\text{pre}}}\right)
\]

C\text{post}: postdialytic urea concentration/C\text{pre}: predialytic urea concentration

In view of the simplicity of the method, URR is frequently used to determine the dose of dialysis, despite the fact that the method has an in-built analytical weakness which may cause inaccurate results. In contrast to other methods, the URR method does not take into account that urea is also removed from the blood by ultrafiltration.

Ultrafiltration leads to a very efficient transfer of urea from the blood into the dialysate, but this does not result in a direct reduction of the urea concentration in the blood. This removal of urea is not accounted for in the URR method. The greater the UF volume removed during dialysis, the more inaccurate the results of dialysis dose calculation based on URR\(^{(2,3)}\).

2.1.2 Kt/V

The formula Kt/V, which is the most commonly used index of the adequacy of the dialysis treatment, is a mathematical representation involving the blood volume which has been completely cleared of urea during a specified dialysis and the urea distribution volume of the patient requiring detoxification. \(\text{Kt/V}\).

\[
\text{Kt/V} = \frac{\text{Clearance \times Dialysis time}}{\text{Distribution volume}}
\]

The variables of the Kt/V formula:

**Clearance K**

As well as being used as a diagnostic parameter in renal function tests, the term “clearance” is also used in renal replacement therapy. The primary parameter used to determine the volume of blood which has been purified during treatment is the effective in-vivo clearance \(K_{\text{eff}}\) (mL/min) \(\text{2.}\) Clearance is defined as the (hypothetical) volume of blood which has been totally “cleared” of a given substance each minute; clearance is thus expressed as mL/min.
In-vivo must be differentiated from in-vitro clearance:

In-vitro clearance represents the purely diffusive clearance achieved by a dialyser tested under defined conditions (as specified in standard EN 1283) using standardised aqueous solutions. The EN 1283 standard requires that measurements be conducted at a predefined dialysis fluid flow rate without any ultrafiltration (that is, without a convective clearance component). Only on the basis of these non-patient-specific laboratory measurements is it possible to compare clearance values and thus the relative efficiency of individual dialysers. In-vitro clearance, i.e. the efficacy of a dialyser under laboratory conditions, is thus primarily determined by the design features of the dialyser as well as the membrane characteristics.

In-vitro clearances of dialysers, on the other hand, are measured under the actual dialysis treatment conditions involving the patient, generally by means of analysis of the blood prior to and after passing the dialyser: the term “whole blood clearance” is thus used in this context. In-vivo clearances are substantially different from in-vitro clearances as, during the dialysis of whole blood, the effects of the corpuscular blood constituents (mainly the erythrocytes), the dissolved plasma proteins, and the adsorption of plasma proteins on the dialysis membrane (the “secondary membrane”) considerably alters the diffusion properties of the dialysis membrane even under otherwise comparable circumstances.

In-vivo clearance is thus inevitably lower than the standardised in-vitro clearance, but does reflect the actual conditions of the treatment and is thus of central importance for the determination of dialysis efficiency.

\[ K = Q_B \frac{C_{B_{in}} - C_{B_{out}}}{C_{B_{in}}} \]

\( K \) = clearance (mL/min), \( Q_B \) = effective blood flow (mL/min), \( C_{B_{in}} \) = concentration of inflowing blood, \( C_{B_{out}} \) = concentration of outflowing blood

**Effective dialysis time \( t \)**

Effective dialysis time \( t \) is the actual duration of diffusive blood detoxification (time of dialysis fluid flow in the dialyser with the blood pump operating). Interruptions to the dialysis treatment for therapeutic or technical
reasons are considered in the effective dialysis time. The effective dialysis time is, in most cases, shorter than the total duration of treatment provided.

In an observational study, Segura et al. have demonstrated that the mean prescribed duration of dialysis is generally not achieved in practice. Thus, over the period of 1 year, the loss of time and therefore of efficiency per patient was equivalent to that of 7 whole dialysis sessions.

**Urea distribution volume V**

The urea distribution volume V is equivalent to the total body fluid, consisting of the proportion of water in blood (7%) as well as the interstitial (31%) and intracellular volume compartments (60%). Upon commencement of dialysis, urea is homogeneously distributed throughout the body; hence, more than 90% of the urea which accumulates in the human body is not present in blood, but in the interstitial and intracellular volume compartments. Thus, only with continuous diffusion of urea from these compartments into the blood and further transport into the extracorporeal circulation is the largest proportion of urea present in the body made available for dialysis.

The larger the blood volume (high blood flow rate) which reaches the dialyser during a treatment session and the longer the duration of the time-dependent diffusion from the interstitial and intercellular compartments into the blood (adequate treatment time), the more efficient the dialysis treatment will be.

A major advantage of the Kt/V equation is the fact that it takes into account the individual body weight of the dialysis patient. Patients with the same Kt/V are detoxified to the same extent even if they have markedly different body weights. Dialysis treatments can thus be compared in terms of the elimination effect using the Kt/V method.

**The following examples should help explain the use of the Kt/V concept:**

Assuming Kt is 20 litres, this means that 20 L of blood have left the dialyser after being cleared of urea. However, this information does not yet tell us which dialysis dose the patient has received. In the case of a patient with a urea distribution volume V of 30 L, a cleared blood volume of 20 L has quite a different meaning than in the case of a patient with a urea distribution volume of 40 L. If Kt/V is equal to 1, this means that the volume of blood which has been completely cleared of urea in the dialyser is exactly equivalent to the urea distribution volume of the patient. In a patient with a distribution volume of 40 L, Kt must be equal to 40 L so that the result of the formula Kt/V is also 1. If the Kt value is only 20 L, the Kt/V value would be 0.5.

Even if Kt/V is equal to 1, this does not mean that the total body fluid or the total urea distribution volume of the patient is free of urea, but only that, using the example above, 40 L blood have left the dialyser after being freed of urea. If Kt/V is 1.0, a urea concentration of approximately 36 – 37%, relative to the baseline value, remains after dialysis.

**2.1.2.1 Determination of Kt/V using blood samples**

There are various methods which can be used to determine Kt/V in practice. These differ in terms of the underlying mathematical models used to predict and determine urea kinetics (in other words, the changes in the blood urea concentration of the patient over time). Some methods involve very complex calculations and require appropriate software programmes.
Formal urea kinetic modelling

The most complex, but at the same time most precise method of determination of Kt/V is the so-called formal urea kinetic modelling[5,6]. This requires accurate measurement of:

• urea or BUN (Blood Urea Nitrogen): concentrations prior to and after the first dialysis session of the week, and urea or BUN concentrations prior to the second dialysis session of the week (assuming three treatments are provided per week)
• the body weight of the patient prior to and after the first dialysis session of the week
• the actual effective treatment time (not the prescribed duration of dialysis and not the time from connection to and disconnection from the dialysis machine)
• the effective urea clearance of the dialyser as measured at the dialysis centre (not the value for in-vitro clearance quoted by the manufacturer).

Urea kinetic modelling is a reproducible method which not only allows calculation of the dialysis dose Kt/V, but also of the parameter nPCR (normalised Protein Catabolic Rate), an important marker of the nutritional status of the patient. Moreover, urea kinetic modelling allows the exact calculation of the patient-specific urea distribution volume so that the individual dialysis prescription can be given on the basis of measured data.

The main disadvantage of the urea kinetic modelling method is the logistical aspect. Some parameters, such as the effective clearance achieved by a dialyser, are difficult to measure in clinical practice and the effort required to obtain and process the necessary data can be considerable in large dialysis centres.

More recently, a two point urea kinetic model has been validated which is based on only two measurements of urea or BUN instead of three, prior to and after the dialysis session and which supplies precise results with a marked reduction of logistical effort[7].

Single-pool Kt/V (Daugirdas formula)

The best alternative to the urea kinetic modelling method, also based on analysis of blood samples, is provided by the formula for the calculation of Kt/V developed by J.T. Daugirdas[8].

Single-pool variable volume Kt/V

Most widely used at present is the following formula for calculating Kt/V:

\[
\text{Kt/Vsp} = -\ln (R - 0.008 \times t) + (4 - 3.5 \times R) \times \frac{U_f}{W}
\]

In: natural logarithm, R: ratio of postdialytic ÷ predialytic BUN, t: effective dialysis time in hours, Uf: ultrafiltration volume in litres, W: weight of the patient after dialysis in kg.

This mathematical model, which uses the natural logarithm to calculate Kt/V, provides sufficiently accurate results over the full range of standard Kt/V values[9,10]. In addition, the Daugirdas formula takes into account the change in patient volume caused by ultrafiltration and its contribution to convective urea elimination.

![Diagram of urea kinetics](image-url)
Double-pool Kt/V (dpKt/V) and its approximation:
equilibrated Kt/V (eKt/V)

As in the case of the other (not discussed here) single-pool models, the Daugirdas formula considers the body, for the purposes of mathematical modelling as a single unified fluid pool, and does not take into account the differences in rates of urea transfer between the three fluid compartments blood plasma, extracellular space and intracellular space. This difference in the transfer rate of urea is described as the double-pool effect.

With increasing efficiency of the dialyser, it is possible that urea is eliminated more rapidly from the blood than it can diffuse from the cells into the blood. Due to this relative delay of urea movement from cells into blood, the intracellular compartment becomes a non-equilibrated reservoir for urea, and this aspect is not taken into account in the single-pool models for urea kinetics.

Hence, on completion of a dialysis treatment, the intracellular urea concentration is greater than in blood plasma, and the diffusion of urea from cells into blood nevertheless continues for approximately 30 – 60 minutes after the end of treatment. This phenomenon is called urea rebound. If this intracellular urea pool is large on completion of dialysis and is not taken into account, the effective dialysis dose Kt/V will be overestimated. This effect is particularly marked if high performance dialysers are used in combination with a short duration of dialysis.

In addition to the relative delay of transfer of urea between the various body compartments, the marked differences in blood perfusion of organs also contribute to the rebound effect. It should be borne in mind that 70 % of total body water, and thus also urea, is present in body organs with a relatively low blood perfusion, such as skin and muscles at rest. As these urea-rich organs have only a relatively low blood flow, their contribution to the total plasma urea which reaches the extracorporeal circulation is less than that of organs with low urea concentrations but having higher rates of blood perfusion. Organs with low blood perfusion therefore also constitute a further urea reservoir. In the initial 30 minutes after completion of dialysis, the concentration equilibration again leads to a rebound, thus an increase in blood urea concentration.

The extent of total urea rebound can differ greatly between individual patients. In a study conducted by Leblanc et al., the mean rebound, the percentage increase in postdialytic urea concentration 30 minutes after dialysis, in comparison with that immediately after completion of dialysis, was 17 %.

If this rebound effect is taken into account in the calculation of the dialysis dose, the resultant Kt/V value is referred to as equilibrated Kt/V (abbreviated to eKt/V). On average, equilibrated single-pool Kt/V (eKt/V) is 0.2 lower than non-equilibrated single-pool Kt/V.

In order to obtain an exact value for equilibrated Kt/V, the BUN concentration should ideally be measured 30 minutes after completion of dialysis, but this is, unfortunately, not practicable in routine practices of outpatient haemodialysis centres. In order to overcome this problem, various formulae have been developed which, after a third blood (urea) sample has been taken during the dialysis session (usually after 70 minutes dialysis), allow the postdialytic equilibrated urea concentration to be approximately calculated. The additional effort required to obtain a third blood (urea) sample has meant that this method has not been widely accepted.

Daugirdas has also developed a formula which allows the results of calculation of single-pool Kt/V to be extrapolated to equilibrated Kt/V. Formula 1 (eKt/V) is applicable if an arterial postdialytic urea value from an arterio-venous access is available, while formula 2 (eKt/V) should be used if a mixed venous urea value from a veno-venous access is available:

\[ \text{Formula 1: } eKt/V = \text{Kt/V} \]
The key advantage of these formulae is that only two blood samples are required for the calculation of the equilibrated Kt/V.

The following table shows the relationship between single-pool Kt/V (spKt/V) values and equilibrated Kt/V values (eKt/V) relative to the duration of treatment.

<table>
<thead>
<tr>
<th>eKt/V</th>
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<tbody>
<tr>
<td>spKt/V</td>
</tr>
<tr>
<td>2.0 hrs</td>
</tr>
<tr>
<td>1.0</td>
</tr>
<tr>
<td>1.1</td>
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<td>1.5</td>
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<td>1.6</td>
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In 2002, Port et al. published an observational study of major importance on the effect of delivered dialysis dose on the risk of mortality\(^{(31)}\).

In this retrospective study, the data for 45,967 US patients who had commenced chronic haemodialysis therapy between April 1997 and December 1998 were examined\(^4\).

2.2 The clinical relevance of the dialysis dose

If dialysis dose is determined, it is possible to prescribe and subsequently monitor the dialysis treatment on the basis of clinical parameters. A significant correlation between the average delivered dialysis dose and patient mortality rates has been demonstrated in many clinical studies\(^{(1,21–29)}\). All these studies reiterate the fact that the higher the delivered dose of dialysis, the lower the patient mortality rates.

The NCDS study\(^{(32)}\) was the first long-term study which investigated the correlation between dialysis dose and therapeutic outcome. The results not only demonstrated a statistical relationship between urea elimination and mortality, but also allowed Gotch & Sargent to develop the urea kinetic modelling method and define the Kt/V.

In order to not mask the relationship between mortality risk and dialysis dose by the separate risk factor “body weight of the patient”, patients were initially sorted into three body weight groups – small, medium and large. The relationship between mortality risk and dialysis dose was then analysed separately for each of these body weight groups. The result was confirmed over the whole range of dialysis doses analysed: the higher the delivered dialysis dose, the lower the rate of patient mortality. This study also showed that there is no specific maximum dose above which no further decrease in patient mortality can be achieved. This means that during each dialysis treatment, it is advisable to deliver the highest dialysis dose possible.

Other clinical aspects, such as the erythropoietin (EPO) requirement, can also be influenced by the dialysis dose Kt/V. In a study published in 2001, the EPO requirement of two patient groups with different Kt/V values
was compared\(^{(32)}\). Measured haematocrit was identical, at 35 ± 1.5\%, in the two investigated groups, A and B, although group A received dialysis at a low Kt/V <1.2 and group B received dialysis at a high Kt/V >1.4. While group A (Kt/V<1.2) had an EPO requirement of 183 ± 95 U/kg/week, patient group B with its high Kt/V (>1.4) required only 86 ± 33 U/kg/week. This study shows that if a sufficiently high dialysis dose is delivered, this can have a positive effect on the overall clinical condition of the patient, which, in turn, is reflected in a reduction of the EPO requirement.

2.3 Recommendations for dialysis dose and the frequency of measurement of delivered dose

As a general rule, it is the task of the treating nephrologist, to prescribe the form and dose of dialysis treatment, taking into account the specific clinical factors of the individual patient.

A very comprehensive collection of recommendations for the prescription of dialysis was first provided by the US National Kidney Foundation (NKF) in their guidelines on adequate haemodialysis treatment. The DOQI guidelines were published in 1997 and subsequently updated as the K/DOQI guidelines (Kidney Disease Outcomes Quality Initiative) in 2000\(^{(33)}\). The European Best Practice Guidelines for Haemodialysis (EBPG Part1) were introduced in 2002 and represent the current consensus on best practices and dialysis adequacy amongst the European nephrological community\(^{(67)}\).

The respective recommendations regarding dialysis dose are specified as follows:

- The delivered dialysis dose should be regularly measured and monitored – at least monthly using a standardised method
- The delivered dialysis dose should be expressed as equilibrated Kt/V (eKt/V) or as single-pool Kt/V (spKt/V)
- The minimum dose per session on a thrice-weekly schedule should be eKt/V ≥ 1.20 (spKt/V ~ 1.4)

The EBPG for Haemodialysis are considered to be the reference guidelines in Europe and have been adopted or taken as the basis for the preparation of national guidelines.

It has become one of the main aims of haemodialysis treatment, particularly in the US, to deliver a high Kt/V dialysis dose. In the US, the average delivered Kt/V dialysis dose continuously increased in the period 1986 to 1999 from 0.9 to today’s figure of greater than 1.4.

The prescription of an adequate Kt/V not only represents the mathematically standardised specification of a verifiable therapy goal, but is a quality criterion for dialysis therapy itself because of the frequently described direct correlation between dialysis dose and patient mortality\(^{(1, 21 – 29)}\). The regular measurement of delivered Kt/V is thus an important aspect of medical quality assurance. To date, however, the need to extensively sample urea concentrations, and the associated logistical and financial requirements, has made it difficult to conduct close monitoring of dose or even to measure delivered dose in each session. As an automated procedure, which is not based on a urea/blood sampling method, the Online Clearance Monitoring (OCM)\(^{(69)}\) has made it possible to measure dialysis dose easily without additional expenses during on-going dialysis treatments at every session.
The Online Clearance Monitoring (OCM®) is a standard feature integrated in the Fresenius Medical Care 5008 Therapy System. It provides automatic intradialytic measurement of the delivered dialysis dose Kt/V, the effective in-vivo urea clearance, the accumulated cleared plasma volume Kt and the plasma sodium concentration of the patient. OCM® can be applied during regular ONLINEplus haemodiafiltration treatments in pre or post dilution mode as well as during standard haemodialysis.

The dialysis dose determined by the Online Clearance Monitoring (OCM®) is equivalent to a single-pool Kt/V (spKt/V).

3.1 The method of OCM® operation

To achieve the objective of developing a low cost method of monitoring clearance, it was necessary to move away from the cost-intensive concept of enzymatic urea analysis. In searching for an alternative, a substance was considered which is present in large quantities in the dialysis fluid and where changes in concentrations can be measured by the sensors installed within the dialysis machine – namely ionised sodium. Sodium ions represent the largest proportion of freely mobile electrolytes in the dialysis fluid and their concentration essentially determines the total conductivity of the dialysis fluid.

Although the small, positively-charged sodium ion differs from the non-charged and larger urea molecule, both particles exhibit comparable in-vitro and in-vivo diffusion characteristics across a synthetic dialysis membrane, i.e. their specific diffusion coefficient is almost identical at 37°C (Na+: 1.94 x 10−5 cm²/s, Urea: 2.20 x 10−5 cm²/s) (34). Under real dialysis conditions, the difference in clearance is even smaller than the difference of diffusion coefficients since the clearance is limited by blood and dialysate flow rates and not by the diffusion process across the dialyser membrane.

By means of indirect determination of ion concentrations in the haemodialysis solution (measurement of conductivity at the inflow and outflow of the dialyser) it is technically possible to determine the diffusion profile of sodium ions across the dialysis membrane and thus calculate the dialysance or ionic clearance (D). On the basis of the dialysance of sodium ions, the “diffusibility” of urea through the membrane (permeability) and thus urea clearance can be determined (35).

For accurate measurement of sodium dialysance, conductivity sensor cells have been installed in the inflow and outflow lines of the dialyser to measure the conductivity of the dialysis fluid (prior to the dialyser) and in the dialysate (after the dialyser) (36).
In order to achieve a detectable diffusion of sodium ions across the membrane, the otherwise moderate diffusion gradient of sodium between the blood and dialysis fluid sides of the dialyser must be temporarily increased.

For this purpose, the dialysis machine induces a short term pulse to increase (or decrease) the sodium concentration in the dialysis fluid, thereby resulting in an increase in diffusion of sodium ions into the blood compartment or in the reverse direction. Assuming that the conductivity pulse does not exceed the specified conductivity limits, alternate pulses increase and decrease conductivity to ensure that the sodium balance remains as neutral as possible.

This short-term increase in the conductivity of the dialysis fluid prior to entering the dialyser is subsequently reduced by diffusion of a portion of the sodium ions across the dialysis membrane into the blood of the patient during the passage through the dialyser. The dynamic input conductivity signal (pulse) at the dialyser inflow is continuously monitored by the conductivity sensor installed at that position: the signal at the outflow of the dialyser is registered by an equivalent sensor positioned there. The relative areas under the curves for the two recorded conductivity signals reflect the diffusion of sodium ions across the dialyser membrane. The lower the value of outflow conductivity compared to inflow conductivity, the greater the amount of sodium that has diffused from the haemodialysis solution into the blood compartment as a result of the diffusion gradient or, in other words, the more permeable the dialysis membrane for sodium is.

As urea – as postulated above – has a diffusion profile similar to that of the sodium ion, urea clearance can be determined (using appropriate correction factors) irrespective of the actual concentration of urea in the blood.

Steil et al. were able to demonstrate in 1993 that the dialysance is directly proportional to urea clearance. They showed how closely measured ionic clearance correlates with measured urea clearance. In a validation study conducted in 2001, Kuhlmann et al. produced clinical evidence that dialysance also correlates with urea clearance in vivo, and that it can be determined accurately within a very low analytical error range of only ±5% by the OCM®. As a comparison: the analytical error for the determination of urea in the laboratory is approx. ±7%. In both of the above-mentioned investigations, it was possible to demonstrate that the correlation between electrolyte clearance and the clearance values for urea determined using standard methods is almost ideal. The majority of results lie, with sufficient precision, on the line of identity and the correlation value r is close to the ideal value of 1 (if all values for ionic clearance and laboratory data

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![Diagram](Link to the diagram showing the location of the 2 conductivity cells of the OCM®)

![Graph](Link to the graph showing inlet/outlet conductivity over dialysis time)

![Diagram](Link to the diagram showing the location of the 2 conductivity cells of the OCM®)
clearance were exactly identical, all results would be on the ideal line). The majority of values are within an error range of only ±5 – 6%.

Through further improvements of the Online Clearance Monitoring® method, Goldau et al. reported in a further series of analysis in 2002 an improved level of precision of below the 5% error limit [45].

The precision of the conductivity monitoring is determined, among other factors, by the stability of the plasma sodium concentration during measurement. The less variation in the plasma sodium concentration of the patient during the measurement cycle, the more precise the result is. For this reason, the time interval of conductivity variation is kept as short as possible in the OCM® technique.

With this comparatively short (but still sufficiently long) measurement of dialysate conductivity at the dialyser outflow, not only the sodium dialysance of the dialyser, but also the negative effects of total recirculation (fistula recirculation plus cardiopulmonary recirculation) can be determined [46]. Even after the conductivity pulse in the dialysate has faded out, recirculating blood transports recirculating sodium ions to the dialyser which, depending on the concentration in the blood, will diffuse back into the dialysate. Consequently, this results in a less favourable ratio of the areas under the conductivity curves, and thus to a reduction in clearance equivalent to the contribution made by recirculation. Although it is not possible to produce actual figures for recirculation from the OCM®, the effect is taken into account in the calculation of effective in-vivo clearance.

The OCM® determines clearance “online” during the entire treatment period, i.e. with no time lapse and at predefined measurement intervals. The number of measurement cycles to be performed during the treatment can be pre-selected within certain limits (see 5008 Operator’s Manual). In addition, the OCM® is capable of detecting adjustments to blood and/or dialysate flow rates within 1 minute and then immediately recalculates the corresponding new clearance values. This means that the effects of any alteration to treatment parameters on actual clearance can be continuously monitored during an ongoing session.

In addition to the urea clearance K, the data for the current effective dialysis time t are obtained from the Fresenius Medical Care Therapy System 5008 and are included in the calculation of the dialysis dose. The effective dialysis time t is defined as the time in which physical dialytic processes between the blood of the patient and the dialysate fluid occur. The time of any interruption of treatment for technical or therapeutic reasons and the duration of preparation and reinfusion procedures are not included: only the “true” dialysis time (diffusion time) is taken into account.

On the basis of the two measured parameters – urea clearance and effective dialysis time – the OCM® calculates the cumulative water volume contained within the blood K x t (in litres) which has been cleared of urea, which is equivalent to that proportion of the circulating blood from which all urea has been removed during dialysis: K x t = x (L).
In order that the Kt/V value can be determined by division of the result for K x t by the urea distribution volume V, the operator must enter an appropriate value for the urea distribution volume V of the individual dialysis patient.

The easiest method of estimating urea distribution volume V is to use the anthropometric formulae developed by Watson, Hume-Weyers and Mellits-Cheek, the latter being especially adapted for children below the age of 16. All formulae can be selected in the OCM® menu of the 5008. The Watson formula calculates the V of a patient on the basis of body weight, height, age and gender.

\[
\text{Male: } V_{\text{urea}} = 2.447 - 0.09516 \times \text{age} + 0.1074 \times \text{height} + 0.3362 \times \text{weight} \\
\text{Female: } V_{\text{urea}} = -2.097 + 0.1069 \times \text{height} + 0.2466 \times \text{weight}
\]

The Hume-Weyers formula requires information on body weight, height and the gender of the patient; information on age is not required. For information on the Mellits-Cheek formula please refer to the FAQ section.

Kloppenburg et al. have demonstrated, in a comparative study, that the results for urea distribution volume V calculated using the anthropometric Watson formula regularly exceed the measured V of the same patient by 26% \(^{50}\). Thus, if the value for V obtained using the Watson formula is used instead of a measured value for calculation of Kt/V, the achieved Kt/V is frequently underestimated.
In order to determine an exact value for spKt/V using the OCM®, it is always preferable to enter the measured urea distribution volume rather than an anthropometrically-derived V.

With the software “Dose Calculation Tool” (DCTool), Fresenius Medical Care provides the OCM® user with an uncomplicated and precise instrument for the accurate calculation of patient-specific urea distribution volume V using treatment and laboratory data. The DCTool is a urea kinetic modelling (UKM) software programme based on 2 point urea kinetic modelling. The programme determines the weekly urea profile of a haemodialysis patient based on two blood samples (pre and postdialytic) using the single-pool variable volume method. Important data relevant to the dialysis and nutritional status of the patient, such as urea distribution volume, Kt/V and protein catabolic rate (PCR) are derived from this. The DCTool programme differs from the standard urea kinetic programmes in that, instead of calculating theoretical clearance on the basis of blood and dialysate flow rates, the effective in-vivo clearance – averaged for the treatment as a whole – as measured by the OCM® is used for modelling.

For the determination of the urea distribution volume of a patient using the DCTool, the basic patient data and information on treatment regimen needs to be entered. Then one dialysis treatment is selected and the related main treatment and OCM® data (i.e. the average effective in-vivo clearance) together with the pre- and postdialytic urea values from blood samples, are entered in the DCTool programme. With this information, the DCTool conducts an urea kinetic analysis and determines a precise value for the urea distribution volume V; apart from other very interesting dose and nutritional parameters. Once this assessed value for V is available, it can be entered directly into the OCM® template, saved on the PatientCard and is hence available for subsequent treatments. This enables the OCM® to calculate an exact value for spKt/V with an error <0.1 for each routine dialysis session conducted over a lon-

![DCTool is a urea kinetic modelling software to precisely calculate the urea distribution volume of the patient](image)

12: DCTool is a urea kinetic modelling software to precisely calculate the urea distribution volume of the patient

<table>
<thead>
<tr>
<th>The conventional procedure today</th>
<th>Aspects</th>
<th>5008 with OCM® option</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood samples (expensive)</td>
<td>Kt/V ≥ 1.2... 1.8</td>
<td>Dialysate; K and t (no additional costs)</td>
</tr>
<tr>
<td>Once a month/quarterly</td>
<td>Frequency</td>
<td>In every session</td>
</tr>
<tr>
<td>Retrospective</td>
<td>Control</td>
<td>Continuous, online</td>
</tr>
<tr>
<td>Staff, syringes, lab time, cost and energy</td>
<td>Effort</td>
<td>None</td>
</tr>
<tr>
<td>6 – 8 %</td>
<td>Accuracy of K</td>
<td>6 %</td>
</tr>
<tr>
<td>Inconvenient</td>
<td>Handling</td>
<td>Automatic</td>
</tr>
<tr>
<td>Unpractical and uncommon</td>
<td>Quality assurance</td>
<td>Standard!</td>
</tr>
</tbody>
</table>

13: OCM® offers many advantages in comparison with the conventional method for the Kt/V measurement
ger time period (up to 6 months for stable patients). It is possible to convert this single-pool Kt/V determined by the OCM® to an eKt/V (= double pool Kt/V) using the formulae provided in section 2.1. Alternatively, eKt/V values are also shown in the table 1 on page 10. In order to ensure that the V value is appropriately updated, it is advisable to repeat urea kinetic modeling calculations with DCTool within the framework of routine laboratory tests every 6 – 12 weeks.

In clinical studies in which 40 treatments and 151 treatments were analysed, it was shown that the DCTool-method provided the optimum value for the urea distribution volume of a patient (51,52,66) and that the results agree well with the total body water measured with bioimpedance spectroscopy.

The use of the OCM® functionality and DCTool in combination makes it possible to determine the exact value for spKt/V during each routine dialysis.

The parameters relevant to therapy monitoring, including the OCM® measurement results, are displayed in a clear overview with a multi-coloured diagram on the touch screen of the 5008 Therapy System. The clearance K is displayed during the course of the treatment as a blue line in the “OCM® diagram” graphic, so are the current and absolute values for K, Kt/V or Kt and Goal-Kt/V. In addition, the cumulative Kt/V (red line) or Kt (black line) are visualised in relation to the set Kt/V target (green line).

3.2 OCM® in ONLINEplus Haemodiafiltration treatments

ONLINE Haemodiafiltration (HDF) with its numerous positive effects on uraemia-related cardiovascular risk factors, is acknowledged as the most effective dialysis treatment modality that comes closest to the elimination profile of the natural kidney. In particular, HDF shows superior clearances in comparison to standard haemodialysis in the removal of middle molecules. In selected European countries, up to 30 – 40% of the dialysis population is treated with ONLINE HDF, the average however being around 10% (61).

Several studies have demonstrated clinical advantages of the ONLINE HDF treatment modality such as an increased dose of dialysis, a reduced risk of β2-microglobulin-associated amyloidosis (62,63), a positive influence on the treatment of anaemia (64) and improved intradialytic cardiovascular stability (65). The results of two recent studies even demonstrate that patients treated with ONLINE HDF had a significant 35% reduction of mortality risk compared to patients treated with standard haemodialysis (68,69).

The precision of the OCM® clearance measurement under ONLINE HDF conditions has been validated in-vitro and in clinical experiments by Canaud et al. (Hôpital Lapeyronie, Montpellier, France; publication in Ki pending (71)). In these investigations, an error range of 6% for the clearance measurement of the OCM® system during ONLINEplus HDF was reported.

With the introduction of Online Clearance Monitoring in ONLINEplus Haemodiafiltration it is possible to easily monitor the dose of dialysis during highly efficient, convective treatments.
4. Optimisation of dialysis efficiency

The efficiency of each haemodialysis treatment is determined by the following four parameters:

- the effective extracorporeal blood flow
- the actual dialysis time
- the effective urea clearance achieved by the dialyser
- the dialysate flow rate

It is essential to achieve the appropriate balance of these parameters in order to ensure that adequate dialysis treatment is provided and also to ensure that the resources available are economically utilised.

### 4.1 Blood flow

![Blood flow diagram](image)

The extent of urea clearance achieved during dialysis is determined largely by the effective blood flow rate. Increasing the blood flow rate is thus a very effective method of increasing dialysis efficiency. Figure 15 illustrates that in the blood flow rate range 0 – 600 mL/min, the increase in urea clearance is proportional to the increase in blood flow rate. Under the specified conditions, e.g. with the Fresenius Medical Care FX 60 dialyser, an increase in blood flow rate from 200 mL/min to 400 mL/min results in an increase in urea clearance by 65%, while an increase in blood flow rate from 150 mL/min to 300 mL/min results in an improvement of 82%. But even moderate increases in blood flow rate by 50 mL/min – from 250 mL/min to 300 mL/min – under standard conditions of dialysis lead to an increase in the urea clearance of approximately 15%.

When prescribing the required blood flow, and particularly when increasing blood flow, the individual vascular access of each patient must be considered. The fistula blood flow rate (average flow rate in radiocephalic fistula is approximately 500 – 900 mL/min) should always markedly exceed that of the extracorporeal blood flow rate in the dialyser, otherwise there is the risk that recirculation, which compromises efficiency, may be induced. Recirculation occurs when blood that has already been cleared of toxins flows, counter to the natural direction of flow in the fistula, out of the venous cannula directly into the arterial cannula and mixes with non-purified blood. Recirculating blood has only a low toxin load prior to its repeated passage through the dialyser. As a result, the toxin removal per time unit is reduced and dialysis efficiency decreases.

There are, however, various devices available, such as the Blood Temperature Monitor (BTM), obtainable as an optional extra to the 5008 Therapy System, which can automatically measure recirculation at a pre-selected blood flow rate. In case of a significant drop in the measured clearance values (≥ 20%) during the same treatment or compared to the previous one stored on the 5008 PatientCard, a BTM recirculation measurement can be automatically initiated by the OCM®.
Since the OCM® conducts the clearance measurement on the dialysate side only, the accuracy of $K$ is not influenced by deviations in the blood flow rate. In the case of blood or dialysate flow changes in between two subsequent measurements, the OCM® is able to account for these changes by using a mathematical estimate for $K$ under the new conditions.

4.2 Dialysis time

As the dialysis time $t$ is a direct variable in the $Kt/V$ formula, it is important to ensure that a sufficiently long effective dialysis time is delivered to ensure provision of an adequate dialysis dose. It is essential to prescribe a sufficiently long treatment time which, by avoiding all interruptions caused by alarms or other delays, should, as far as possible, also represent the effective dialysis time.

The DOQI guidelines, for example, take into account the discrepancy between prescribed and effective treatment time, which frequently occurs as a result of undesirable interruptions in the dialysis treatment, by recommending prescription of a slightly increased $Kt/V$ value of 1.3 if a $Kt/V$ of 1.2 is to be achieved. In a study published in 2001, J. Leon et al. investigated the dialysis prescriptions for 721 dialysis patients. They found that in 15% of patients the dialysis prescription was too low to achieve the minimum dose of $Kt/V$ 1.2 as recommended in the DOQI guidelines. They also concluded that in this patient group, a prolongation of treatment by up to 30 minutes (depending on patient) would have resulted in the delivery of an adequate dialysis dose in 75% of the cases.

This result shows that even a moderate prolongation of treatment time can be an essential factor in ensuring delivery of an adequate dialysis dose. Individual prolongation of treatment time should thus seriously be taken into consideration, despite the difficulties of incorporating this in shift schedules and the unwillingness of patients to an increase in the dialysis time.
4.3 Dialyser
(Membrane surface area, low flux/high flux)

The dialyser itself plays an important role in the efficiency of dialysis treatment. The use of a dialyser with the highest possible urea clearance is required for optimisation of the dialysis treatment. As a representative of other low molecular weight substances, urea is one of the most important marker substances in dialysis.

The urea clearance is not only determined by the active surface area of the membrane, but also by the membrane permeability (high or low flux) and the construction of the dialyser itself. Figure 16 shows the increase in urea clearance under the given conditions (blood flow rate: 300 mL/min, dialysate flow rate: 500 mL/min) in relation to an increase in the effective membrane surface area. Under identical conditions, urea clearance is improved by changing from low flux to high flux dialysers. To utilise a given dialyser to its full capacity, it is important to consider the relationship between effective surface area and the achievable blood flow (see instructions for use: recommended blood flow range).

In many dialysis centres, a dialysis fluid flow rate of 500 mL/min is used by default in haemodialysis treatments, although optimal solute clearances would already be achieved at lower dialysis fluid flow rates. As shown in figure 17, at a dialysate flow rate equal to the blood flow rate, approximately 90% of the maximum solute clearance is already achieved. Thus, much higher dialysis fluid flow rates would not significantly contribute to increases in clearances and are therefore not necessary from an economical point of view.

The 5008 Therapy System offers the AutoFlow function, which automatically adjusts the dialysis fluid flow rate in order to derive an optimal ratio between blood flow rate and dialysis fluid flow rate. Any potential effects on low molecular (e.g. urea) clearance can however be monitored with OCM®, thus providing another very meaningful function for further treatment optimisation, e.g. by means of increased blood flow and/or performing ONLINE HDF.
The prerequisite for an effective dialysis treatment is an appropriate balance between blood flow rate, dialysate flow rate, treatment time and the dialyser used.

For this purpose, Fresenius Medical Care has developed appropriate software in the form of the Clearance Calculation Tool (CCT), which makes it possible to compare the efficacy of Fresenius Medical Care dialysers under diverse predefined treatment conditions.

18: The CCT Clearance Calculation Tool is a software for the planning of haemodialysis treatments. CCT allows a clearance estimation of any Fresenius Medical Care dialyser over the full range of treatment conditions.
In addition to the delivered dialysis dose, the OCM® also measures the level of plasma sodium of the patient. This information is a useful aid in the appropriate therapeutic adjustment of the sodium concentration of the dialysis fluid to the individual plasma sodium level of the patient.

In a clinically stable haemodialysis patient, there is physiological equilibrium between the quantity of salt ingested with the nutrition and the quantity of NaCl removed during haemodialysis.

There are two mechanisms of intradialytic removal of NaCl: ultrafiltration (UF) and diffusion.

The electrolyte composition of the ultrafiltrate removed for the purposes of dehydration of the patient is very similar to that of blood plasma, the NaCl concentration in the ultrafiltrate varies from patient to patient in the approximate range 135 – 140 mmol/L. The quantity of NaCl removed during ultrafiltration depends directly on the volume of UF removed; the higher the volume of UF, the greater the quantity of NaCl removed from the patient.

Diffusion is even more effective than ultrafiltration in the removal of NaCl, though in this case maintenance of an effective concentration gradient between blood and dialysate sides is required.

If the concentration of NaCl available for free diffusion in the blood plasma of the patient is higher than in the dialysis fluid, there is a flow of NaCl from blood into dialysis fluid; NaCl is removed from the patient. The opposite can, of course, also occur: if the concentration of NaCl in the dialysis fluid is higher than in blood plasma, it diffuses from the dialysis fluid into the blood and there is dialysis-induced salt-loading.

The concentration of sodium in the dialysis fluid thus determines whether the sodium balance is positive or negative during haemodialysis treatment.

Various studies have demonstrated that restriction of sodium intake has a favourable effect on long term blood pressure control in dialysis patients; low sodium content in the dialysate, provided this is tolerated by the patient, can assist in dietary control of sodium intake. Krautzig et al. have demonstrated that with low sodium intake, it is possible to reduce, or even discontinue, the use of anti-hypertensive medication.

However, if a dialysate with a non-physiological, low sodium concentration is used, this can frequently trigger intolerance reactions, such as hypotension, tiredness and cramps.

Conversely, the use of a dialysate with a non-physiological, high concentration of sodium may improve blood pressure stability during dialysis, but also increases the patient’s thirst and results in a subsequent increase in fluid intake by the patient. This, in its turn, leads to increased overhydration and long-term hypertension in the patient. Figure 20 summarises the advantages and disadvantages of high and low sodium concentrations in the dialysate.

Individual prescription of the sodium concentration of the dialysis fluid always requires achieving a compromise between long-term beneficial blood pressure control (with low dialysis fluid sodium) and the short-term advantage of better cardiovascular stability during treatment (with high dialysis fluid sodium). Hence, when
deciding on the optimum concentration of sodium in the dialysis fluid, the nephrologist should consider the predialytic plasma sodium, the general status and the cardiovascular stability of the patient.

Figure 20 shows the effects of a haemodialysis treatment on the plasma sodium concentration in individual patients (mean values for 10 treatments are quoted).

While there was little fluctuation in plasma sodium levels in patients 1 and 2 (the dialysis fluid used for both these patients had a sodium concentration of 140 mmol/L), plasma sodium levels in patients 3 and 4 (here the specified dialysis fluid sodium concentration was 142 mmol/L) increased by 2.5 – 3 mmol/L during dialysis.

How can the OCM® be used for measurement of plasma sodium?

The OCM® determines sodium concentrations at the dialysate inflow and outflow by monitoring conductivity. The difference between the two values, in relation to the dialysate flow rate, shows the rate of flow of sodium into or out of the patient. Using the value for clearance as measured by the OCM®, the plasma concentration of sodium can be calculated. In this way, the OCM® derives a value for plasma sodium from each clearance measurement. The result is adjusted using correction factors so that the displayed value for plasma sodium is equivalent to that obtained by means of flame photometry assay.

Small absolute differences between the plasma sodium concentration determined by the dialysis machine using this non-invasive method and the results of laboratory analysis can be explained by deviations of the measurement and calibration instruments used. Of more clinical relevance, however, is the change in plasma sodium concentration during dialysis – with its associated effects – relative to predialytic baseline plasma sodium. Using the data for changes in plasma sodium over time registered by the dialysis machine, it can be determined whether the patient is being loaded with sodium from the dialysis fluid (plasma sodium concentration increase) or whether too much sodium is being removed from the blood (plasma sodium concentration falls), or whether the sodium concentration of the haemodialysis solution is appropriate for the patient (e.g. a tendency to constant plasma sodium concentrations). Online Clearance Monitoring (OCM®) can assist to appropriately adjust the sodium concentration of the haemodialysis solution during the ongoing treatment.

The plasma sodium concentration over time is displayed as a red line in the UF-Na-Diagram of the 5008. At low flow conditions ($Q_B \leq 80$ mL/min; $Q_D < 300$ mL/min), the plasma sodium concentration is not displayed. The accuracy of the value displayed is furthermore strongly affected by the existence of fistula recirculation.

[Image of plasma sodium profile of 4 HD patients measured by OCM®]

[Image of kinetics of plasma sodium concentration in the course of a HD treatment can be displayed by the OCM® (red line)]
1. Is Kt/V as measured by the OCM® a single-pool or double-pool Kt/V?

The Kt/V value determined by the OCM® is a single-pool Kt/V (spKt/V). It is possible to convert the single-pool Kt/V determined by the OCM® to an eKt/V (= equilibrated or double pool Kt/V) using the formulae provided in Section 2.1.2.1 Alternatively, eKt/V values are also shown in the table on page 10.

2. In a comparison conducted at a dialysis centre, it was observed that the OCM® Kt/V was 10% lower than the Kt/V measured on the blood side: what is the cause of this discrepancy?

Such a difference is frequently seen if the value for urea distribution volume V used for Kt/V calculation by the OCM® has been estimated using the Watson formula. The anthropometric Watson formula tends to overestimate the urea distribution volume in dialysis patients. As the precisely measured result for K x t determined by the OCM® is then divided by an incorrectly high value for V, this results in an underestimation of the delivered dialysis dose (Kt/V). This problem can be avoided if the value for V is determined more precisely using a bioimpedance spectroscopy (BIS) technique or urea kinetic modelling (e.g. with the aid of DCTool) – see Section 3 – and this value being entered into the OCM® and stored on the PatientCard for future use.

3. What is the significance of haematocrit for the calculation of clearance and plasma sodium concentrations? What alternative is there if no recent value for haematocrit is available for a patient? Could an estimated value for haematocrit result in an inaccurate result for Kt/V?

The haematocrit is required to calculate the effective flow of water contained within the blood (= plasma water + intracellular water) and subsequently the effective Kt/V (Comment: Hct does not have any influence on K, since only dialysate-side quantities are used to determine it. Rather, it enters the estimation formula in case of a blood flow change between 2 measurements). If an estimated Hct which deviates from the actual Hct of the patient is entered in the OCM® template, this will have little effect on the accuracy of the value for clearance calculated by the OCM®. If, for example, the entered value for Hct is 10% higher or lower than the actual value for Hct, there is only a 2 – 3% change in the result for clearance. If no value for Hct is entered prior to commencement of treatment, the OCM® automatically assumes a hypothetical value of 35%. In case a 5008 Blood Volume Monitor (BVM) is used simultaneously with the OCM®, the continuously measured Hct value can be automatically transferred from the BVM to the OCM®.

4. Why is the clearance measured by the OCM® frequently lower than clearance measured on the blood side?

This occurs if a simplified method of whole blood clearance measurement is performed on the blood side, where the full blood flow value Q_b is used for blood side calculation of clearance, while the OCM® correctly uses the effective flow of water contained within the blood (= plasma water + intracellular water). The effective flow of water contained within the blood is equivalent to the effective blood flow x 0.87. The factor 0.87 takes into account the characteristic composition of human blood. If the effective flow of water contained within the blood is not used for blood side calculation of clearance, there can be an inappropriate overestimation of urea clearance by up to 25% compared with the effective clearance which is accurately measured by the OCM®.

5. Could the accuracy of OCM® measurements be impaired if equipment is not disinfected between each dialysis treatment?

In theory, throughout dialysis deposits may occur on the conductivity sensors of the OCM® just as in any of the other components of the hydraulic system of a dialysis machine. To avoid this problem, it is mandatory to disinfect the equipment after each dialysis session.
The risk of an inaccurate clearance measurement is thus excluded.

6. Does the accuracy of the OCM® depend on the membrane material used in the dialyser?

No evidence has been found to date that the accuracy of the clearance measurement by the OCM® is influenced by the type of dialyser membrane used.

7. Can OCM® measurement be started during on-going dialysis treatment?

In principle, the OCM® can be started at any time during on-going treatment. If, however, more than 80 minutes have passed since treatment was started without a successful OCM® measurement performed, the system will not calculate Kt and Kt/V. It would not be worthwhile extrapolating backwards, as there may have been marked changes in clearance since the initiation of treatment.

8. Is it possible to calculate the urea distribution volume of children using the Watson formula?

The Mellits-Cheek formula rather than the Watson formula should be used for anthropometric estimation of V in children:

For boys with a height < 132.7 cm:
\[ V = -1.927 + 0.465 \times \text{body weight (kg)} + 0.045 \times \text{height (cm)} \]

For boys with a height > 132.7 cm:
\[ V = -21.993 + 0.465 \times \text{body weight (kg)} + 0.209 \times \text{height (cm)} \]

For girls with a height < 110.8 cm:
\[ V = 0.076 + 0.507 \times \text{body weight (kg)} + 0.013 \times \text{height (cm)} \]

For girls with a height > 110.8 cm:
\[ V = -10.313 + 0.252 \times \text{body weight (kg)} + 0.154 \times \text{height (cm)} \]

In order to obtain a precise value for V in children, a bioimpedance measurement or urea kinetic modelling (e.g. with DCTool) is preferable.

9. How does one take into account an amputation when calculating urea distribution volume?

Urea distribution volume V in amputated dialysis patients should not be estimated using anthropometric formulae (such as the Watson formula), but should be determined by a bioimpedance measurement or urea kinetic modelling (DCTool).

10. Can OCM® also be used during ONLINE HDF?

OCM® can be used during regular ONLINEplus Haemodialfiltration treatments in either post- or predilution mode but due to the missing dialysate flow in the dialyser not in ONLINE-HF nor in Single-Needle modes.
References


34. Bab A, Maurer C, Popovich R, McKee: The determination of membrane permeabilities and solute diffusivities with applications to hemodialysis. Chem Eng Progr Symp Ser 1968; 64: 59-68


