

Dry-concentrate production systems for dialysis



Mark Power BEng MSc MIEI, Technical Services Manager, B. Braun Medical Ireland Ltd, outlines the operation of dry concentrate production for dialysis and the advantages it offers

Acid concentrate is a key component of dialysis fluid (dialysate), which is required in large volumes for every haemodialysis therapy.

A dialysis machine mixes acid concentrate with alkaline bicarbonate and water of a suitable grade (ISO 13959:2014) to produce fresh dialysis fluid. The dialysis fluid is prepared according to the individual patient's needs to help regulate electrolyte and acid-base balance and remove metabolic waste products.

The vast majority of dialysis centres in Ireland use acid concentrate in ready-to-use liquid form. Conventionally, this has been supplied in 5L or 6L canisters suitable for individual treatments or in bulk containers (800L +) for use with a central delivery system. This practice results in the transportation of vast volumes of fluid (consisting mainly of water) across long distances, adding to both the expense and carbon footprint of every dialysis session. In a dry concentrate system, the acid concentrate is supplied in powder form usually contained in a sealed drum.

The powder is mixed with water of a suitable grade to produce liquid acid concentrate which is then supplied to the dialysis machines via a central delivery system. ISO13958:2014 specifies the requirements for acid concentrates (both liquid and dry) to be used for haemodialysis and related therapies. Production of acid concentrate from dry powder is a well-established practice, commonly used in dialysis centres throughout mainland Europe. Dry concentrates currently represent 35% of acid concentrate use in Germany, and with the increasing momentum towards green dialysis, this number continues to rise. Historically, however, the approach has been slow to gain popularity in Ireland. With the latest generation of fully automated, acid-concentrate mixing systems, dry concentrates can now offer unique benefits to dialysis centres that embrace this new technology.

Installation in Wexford

The first dialysis treatments took place at the newly built B. Braun Wellstone Clinic, Wexford (see Figure 1) on January 17, 2018. This renal care centre is Ireland's first purpose-built dialysis therapy facility in the chronic care setting. This allowed us the opportunity to investigate the latest innovations in dialysis technology and novel design features for inclusion in our new facility. The incorporation of a fully automated, dry-concentrate production system was an easy decision due to efficiency gains, the ease of use for staff, reduction of storage areas and positive environmental impact.

Over two days in early January, we installed, commissioned and began operating an 'EcoMix Revolution' dry-concentrate production system. This fully automated, next-generation system represents Europe's newest technology in dry-concentrate production and is one of the first 20 such systems in use worldwide. The EcoMix system can be configured in many forms, with differing numbers and sizes of holding tanks. We opted for a two-concentrate system with two 860L holding tanks for each concentrate type (see Figure 2).

A single EcoCart cartridge provides 800L of acid concentrate and takes the EcoMix system four to six hours to prepare

depending on permeate loop capacity. Mixing can commence during dialysis treatment times as the system will only draw on available excess permeate without any interruption to treatments. The EcoMix SmartCoupling connectors (see Figure 3) ensure a fast and easy connection between the EcoCart and EcoMix, while simultaneously the radio-frequency identification (RFID) tag, integrated into the drum, identifies the concentrate name, the concentrate chemical formation and the exact volume of permeate required for the batch.

The EcoMix Revolution also allows technicians to access the system remotely, offering real time information on the levels in each storage tank. A full audit history of all previous batches mixed by the system is automatically recorded and available for review if required. We also maintain a paper-based protocol for each batch mixed, which are kept locally with clinic records.

Mechanism of action

The workflow for a fully automated system, the EcoMix Revolution, is described in Figure 4.

1. Firstly, the operator connects the EcoCart powder cartridge to the EcoMix device by attaching the two SmartCoupling connectors to the top



Figure 1: Artist impression of the newly opened B. Braun Wellstone Clinic, a renal care centre located in Wexford.

of the EcoCart. Through an RFID tag integrated into the EcoCart, the system recognises the concentrate name and its chemical composition. This information is displayed on the control panel for confirmation by the operator before concentrate mixing can begin.

2. The system draws in water of a suitable grade from the dialysis centre's water treatment system to fill a mixing tank. It uses only available excess permeate, and does not compromise any ongoing dialysis treatments.
3. The powder contents of the EcoCart cartridge are completely dissolved and thoroughly mixed.
4. All of the concentrate is now in the mixing tank, and the EcoMix device performs a density calculation (DensiCon Technology) on the contents of the mixing tank. The density measurement confirms thorough and correct mixing has occurred and verifies the ex-factory dry powder quantities and specific liquid volume to ensure ISO13958 standard concentrate is produced.
5. The newly mixed concentrate is then automatically transferred from the mixing tank to a storage tank connected to a central delivery system for the dialysis centre. The EcoMix system intelligence ensures only the programmed concentrate type can be transferred to the appropriate storage tank.
6. The user disconnects the empty EcoCart cartridge, which can be returned for reuse.

Quality control

A number of measures are in place to ensure the quality of the concentrate produced by the EcoMix system. In production of the EcoCart cartridges, only pharmaceutical grade raw materials are used. The EcoCart filling process involves double weighing of all ingredients and is fully automated to minimise the possibility of human error. The dry powder contents of the EcoCart are controlled to a tolerance of within $\pm 0.2\%$.

The EcoMix system ensures the correct amount of water is used for each mix and that the contents of the EcoCart have been completely liquefied. The final concentrate composition is validated with temperature-compensated density measurements performed by the density-temperature-filling (DTF) level sensor (see Figure 5). Two density deviation measurements are performed: absolute, based on theoretical value, to $\pm 0.3\%$; and relative, based on the average of the last five mixes of the same concentrate type, to $\pm 0.06\%$.

Advantages

Next-generation dry-concentrate production systems offer many advantages over conventional ready-to-use liquid

concentrates. Principal among these are efficiency gains from simplified handling and reduced logistics. Dry concentrate systems reduce storage requirements in dialysis units, offer easy handling to operators and are environmentally-friendly through reduced transport weight and negating the need to ship bulk fluids across the Irish Sea and further afield.

In addition, the powder containers are reusable. Crucially, current state-of-the-art, fully-automated systems offer levels of secure quality assurance unattainable with previous generation systems.

Future outlook

Modern automated dry concentrate production systems make a convincing

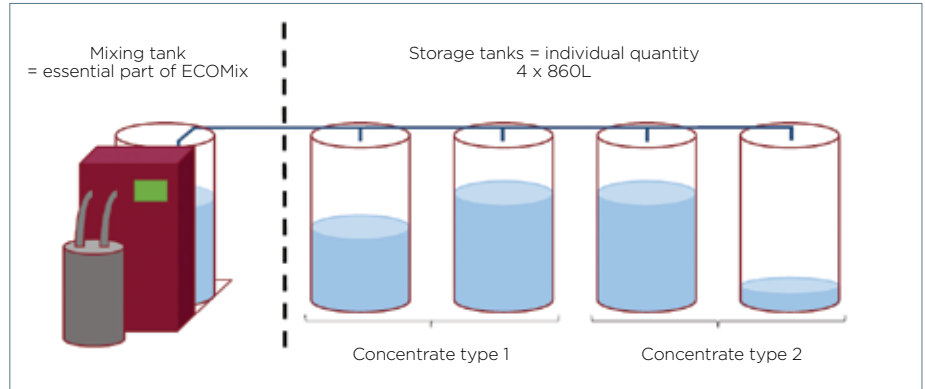


Figure 2 (a): Schematic of an EcoMix system with four holding tanks used to supply two types of central concentrate to a central delivery system.



Figure 2 (b): The actual EcoMix system after installation at B. Braun Wellstone Clinic, Wexford.



Figure 3: The EcoCart powder cartridge is supplied in a sealed drum placed on an integrated trolley for safe and easy movement. Connecting the EcoCart to the EcoMix device is extremely straightforward with built-in controls to avoid input errors. Empty EcoCart containers are reusable.

argument in terms of economic and environmental considerations, as well as usability. B. Braun have plans to introduce a second EcoMix Revolution system at our newest renal care centre in Portlaoise, on which construction will begin this year. When afforded the opportunity to design a new dialysis unit from early planning

stage, the advantages of dry-concentrate production are obvious and I would expect the number of these systems in Ireland to grow. The real challenge will be for existing dialysis units to adapt or convert their current systems to an automated dry-concentrate production model. The same

benefits are available to existing dialysis units that opt to retrofit systems but, to date, no dialysis unit in the Republic of Ireland has yet made the change. Perhaps, the B. Braun Wellstone Clinic could serve as a reference site for other units, who may also be convinced of its benefits once they can see it in action.

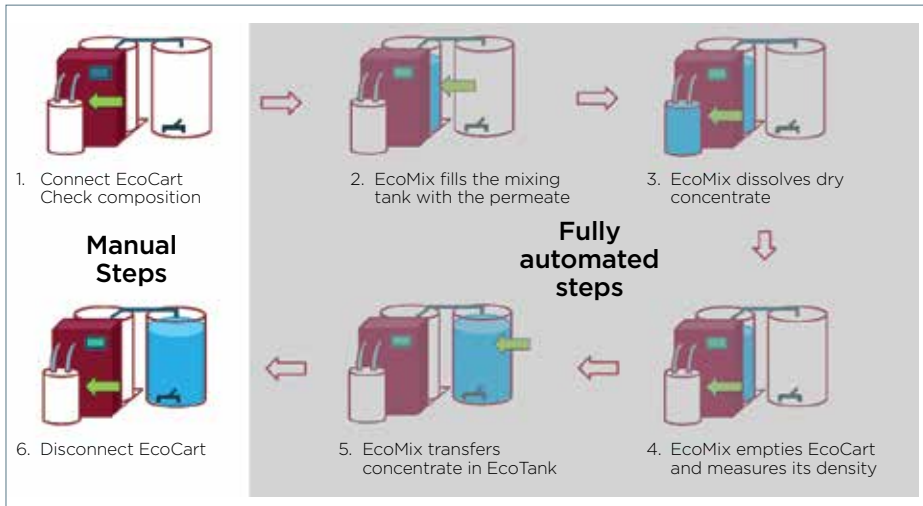


Figure 4: Workflow of the EcoMix Revolution mixing device for acid concentrates. User interaction is only required to connect and disconnect the EcoCart powder cartridge. The rest of the process is fully automated and controlled by the EcoMix system.

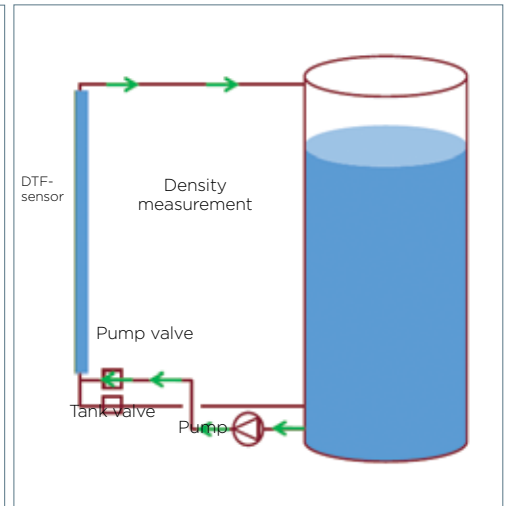


Figure 5: The DTF sensor performs correlation measurements on the density of the contents of the mixing tank.

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