

Baxter gets FDA clearance for dialysis system

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Baxter International has announced that the United States Food and Drug Administration (US FDA) has granted 510(k) clearance for the AMIA automated peritoneal dialysis (APD) system with the SHARESOURCE web-based remote connectivity platform to provide peritoneal dialysis (PD) for the treatment of end-stage renal disease (ESRD).

The AMIA APD system is the only device cleared in the United States that incorporates patient-centric features such as voice guidance, a touchscreen control panel and the SHARESOURCE two-way connectivity platform. SHARESOURCE allows physicians to more readily access their home patients' historical treatment data and deliver individual prescriptions remotely. The system also features advanced, animated graphics and automated step-by-step instructions, which were designed to increase the efficiency of home therapy training and administration for ESRD patients in the United States.

There are more than 600,000 prevalent cases of individuals living with ESRD in the United States. People living with ESRD require dialysis treatment or a kidney transplant to stay alive. PD therapy is typically managed by patients in their home, at a time of day that is convenient for them. It works by cleaning the blood of toxins and removing extra fluid through the body's peritoneal cavity.

The AMIA APD system was developed in collaboration with DEKA Research and Development Corporation (DEKA) to support home PD therapy patients with more intuitive device operation, while providing two-way, web-based remote connectivity with their physicians through Baxter's SHARESOURCE platform. SHARESOURCE also reduces the manual collection of treatment data and organizes records for easy access by healthcare providers.

"Enabling patients to actively work with their healthcare providers to initiate and confidently manage their dialysis therapy is the ultimate goal in the development of AMIA with SHARESOURCE. Baxter's focus is to understand and support access to the best renal replacement options for all patients, and then bring technology like AMIA and SHARESOURCE to healthcare providers so they can help their patients achieve their best possible outcomes," said Dr Bruce Culleton, vice-president, renal

therapeutic area lead, Baxter.