

sagentia

# CHF solutions, Inc

A non-pharmaceutical therapy  
for CHF fluid overload



a science group company

CHF solutions is a manufacturer of medical devices for cardiac care. They came to Sagentia for help with the development of an innovative medical device that removes fluid from the blood of congestive heart failure patients with fluid overload. The Aquadex console continuously withdraws blood from the patient, controls the fluid filtration rate, and returns the blood back to the patient.

In contrast to fluid reduction by diuretic or inotropic drugs, this system enables the medical practitioner to perform precise fluid extraction that is tailored to an individual's need. By removing excess salt and water in a rapid and controlled manner, the Aquadex system enables the focus to be on treating the underlying clinical condition.

We assisted CHF solutions with the electronics and software of its Aquadex system console. This ISO 13485 compliant medical product development spanned hardware and software specification through to development and formal design verification. The combined expertise of our team of electronics, software and mechanical engineers enabled CHF to demo its first fully functional and assembled prototype within 9 months.

The Aquadex console is a microprocessor-controlled device comprising:

- ↳ a pump for blood extraction and return
- ↳ a pump for filtration
- ↳ a dual servo motor controller
- ↳ a keypad and ¼ VGA display for the graphical user interface
- ↳ flash memory for easy field upgrades
- ↳ a load cell to accurately measure rate of fluid removal
- ↳ an intelligent battery charger with fuel gauge
- ↳ sensor interfaces to the disposable components of the system

Our engineers recommended a multi-processor design to address the need for extensive safety monitoring and fault tolerance which minimised the need for specialised and complex circuitry. This distributed approach to control and safety provided easy re-configuration and included a 32-bit processor for system control, an 8-bit processor for redundant monitoring of patient safety and an 8-bit processor for power control and battery management.

Aquadex was launched into the market in 2003 and received FDA approval in June 2002 within two years of project start. Early the following year, the product won the Gold Medal in the prestigious Medical Design Excellence Award in the General Hospital Devices and Therapeutic Products category.