

AWARD-WINNING TECHNOLOGY PRODUCES GOLDEN RESULTS

CHF Solutions

Headquartered in Brooklyn Park, Minnesota, CHF Solutions is a medical device designer and manufacturer, specializing in the area of fluid overload. Fluid overload results in excess fluid collecting in the lungs and lower limbs. It can be caused by many health conditions including congestive heart failure (CHF), which affects approximately 27 million people. CHF Solutions' Aquadex FlexFlow, won the prestigious Gold 2004 Medical Design Excellence Award (MDEA) in the general hospital devices and therapeutic products category.



Safely Removing Excess Fluid

The Aquadex FlexFlow is CHF Solutions' answer to safely, and cost-effectively, removing excess fluid in patients. Prior to the FlexFlow standard IV diuretic drugs were cautiously used and often took four to six days to accomplish what the FlexFlow does in eight hours. This rapid yet controlled system of fluid removal may dramatically reduce the patient's stay and required medical resources.

In the development process, CHF Solutions needed a disposable serial memory device to integrate into the Aquadex FlexFlow. The requirements for the memory device included:

- ✓ A fully engineered off-the-shelf serial memory device that allows communication with the circuit
- ✓ Ability to withstand the harsh environments of hospitals (i.e. chemicals, sterilization, etc.)
- ✓ Ability to cost-effectively perform limit-use functions and then be discarded
- ✓ Reliability—a "key" factor for medical devices used on patients



The Token is a "Must-Have"



The engineers on the FlexFlow project designed their product so that the Datakey Electronics Token is required in order for the unit to function. Two disposable items are tethered together—the circuit and the Token. The Token allows the circuit to communicate the appropriate treatment to the console by identifying the lot number, verifying that it is a valid circuit and establishing when the circuit started treatment. As each circuit is currently indicated for eight hours of use, the Token tracks the time per circuit. At the appropriate 8 hour period, the user is informed and is allowed to make the clinical decision to end or continue. Because of the ability to pre-program the Tokens:

- ✓ Simplicity of operation is maximized
- ✓ Risk of potential error in reprogramming is eliminated
- ✓ Patient's stay is shortened
- ✓ Medical costs are dramatically reduced

Fully-Engineered

Datakey Electronics met the challenge successfully with their SST2Kb Serial Memory Tokens which contain non-volatile, serial SPI EEPROM memory. The SR4210PCB is the mating receptacle. It offers a detent mechanism that gives the user tactile confirmation when an inserted Token is physically engaged, as well as a LOFO contact that may be



used to protect the host bus by ensuring that Tokens have made secure contact with the receptacle before any signals are transmitted.



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hey Chose Datakey Electronics

The “no room for error” nature of a hospital environment requires that the products used be reliable, fast, user-friendly, cost-effective, and top performers in their field. With that in mind, CHF Solutions chose Datakey Electronics for their award-winning Aquadex FlexFlow. The ruggedness of the tokens provides the ability to withstand the harsh hospital environment. It can also survive the sterilization process the Circuit/Token system must endure. Reliability and long-term support were non-negotiable for CHF Solutions, given their product placement. And the cost of this off-the-shelf disposable solution was important for them to stay competitive in the marketplace. With 30 years of experience in rugged and reliable memory devices, Datakey Electronics was a natural choice for CHF Solutions.

Success Leads to More Success

With the successful implementation of the SST2Kb into the FlexFlow and the performance thereafter, CHF Solutions called on Datakey Electronics again regarding firmware updates.

Datakey Electronics designed and produced the solution. A custom SFX 5V 8Mb Token was implemented, offering the same rugged reliability and easy-to-use benefits of the SST2Kb. This custom application allows them to use the same Receptacle as the initial project to do flash updates to the FlexFlow firmware in the field. This not only adds value to their product, but it also greatly reduces previous in-field firmware update costs.

Now, for the cost of a Token, a stamp and a moment to insert the Token into an envelope, the firmware updates are done, making their product even more valuable in the field and to the healthcare industry.



Datakey[®]
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