Datakey®
The power of memory. Secured.

Award-Winning Technology Produces Golden Results

CHF Solutions

Located in Brooklyn Park, Minnesota, CHF Solutions (now part of Gambro) 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 Solution's Aquadex FlexFlow, won the prestigious Gold 2004 Medical Design Excellence Award (MDEA) in the general hospital devices and therapeutic products category.

Applications:
Authentication
Limit Use
Firmware Updates

Market:
Medical

Challenge

The Aquadex FlexFlow is CHF Solution's 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 sterilization
- Ability to cost-effectively perform limit-use functions and then be discarded
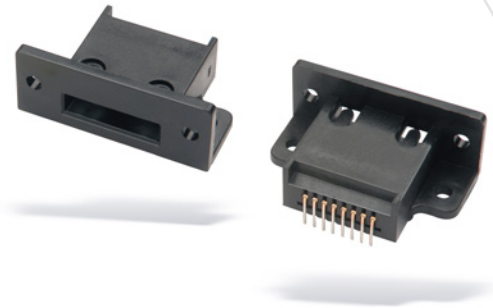- Reliability—a key factor for medical devices used on patients

Solution

The engineers on the FlexFlow project designed their product so that the Datakey 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 intended 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

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Fully Engineered

The chosen solution was to use the Datakey SST2Kb serial memory tokens which contain non-volatile, serial SPI EEPROM memory. The SR4210PCB was chosen for 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 token detection contact that may be used to protect the host bus by ensuring that the token's contacts have made secure contact with the receptacle before any signals are transmitted.

CHF Solutions Chose Datakey

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 a Datakey solution for their award-winning Aquadex FlexFlow system. The rugged design of the tokens allows them to survive the sterilization process the circuit/token system must endure. Reliability and long-term support were critical requirements, and the cost of this off-the-shelf disposable solution was important for them to stay competitive in the marketplace. With over three decades of experience in rugged and reliable memory devices, a Datakey solution was a natural choice for CHF Solutions.

Success Leads to More Success

With the successful implementation of the SST2Kb memory token into the FlexFlow system and the performance thereafter, CHF Solutions wondered if a Datakey memory token could be used for firmware updates. The solution was a custom Datakey SFX 5V 8Mb token which offered the same rugged reliability and ease-of-use benefits of the SST2Kb. This custom application allows for the same receptacle to be used for 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 memory token, postage and an envelope, important firmware updates are done.

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