

Sotera Wireless + The FDA.

Wearable wireless medical solutions are changing the way we think. Eric Topol, M.D., calls them the “the control, alt, delete of medicine.”

Presently in the hospital vital signs are taken every 4 hours. In between those checkups is when problems arise. Sotera Wireless' ViSi Mobile™ is the solution—providing constant data on changes in blood-pressure, heart rate, oxygen saturation, temperature and pulse. The continuous flow of information allows the nurse to respond immediately and prevents life-threatening events.

DDSTUDIO joined forces with Sotera Wireless on the industrial design and mechanical engineering for ViSi Mobile, beginning with detailed ethnographic research. Our first concern was with hospital workflows and how they could be positively affected by a compact, wearable system. The solution had to be good for the nurse, the patient and the hospital.

Images: ① - With Sotera Wireless' breakthrough technology nurses can efficiently monitor a full range of vital signs continuously and remotely throughout the hospital, extending the reach of patient safety and enhancing overall care. This technology is driven by a custom software application package developed by Sotera Wireless, that is compatible with standard Windows-based operating systems.

One extremely important concern was cross contamination: the central elements had to be very easy to clean, with all attachment details designed into the disposable parts.

We solicited the help of a wide group of nurses, viewed existing procedures, and used mock-ups to see how our concepts looked and functioned. A select advisory group offered feedback loops at every stage of the design development.

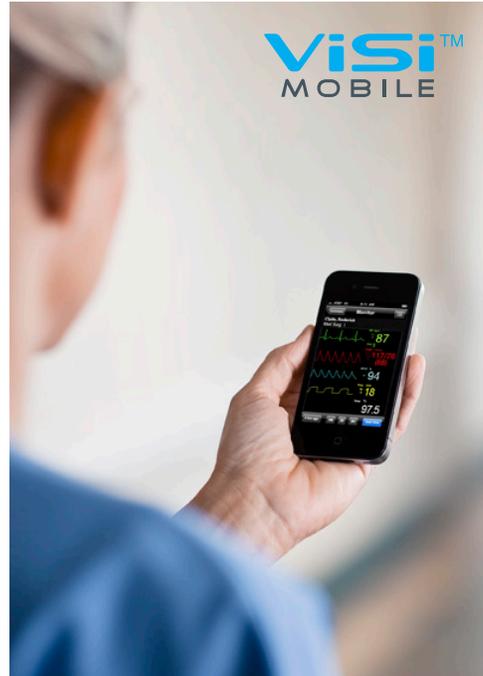
Once the product format was set, complex and extensive mechanical engineering gave us the final solution. The transceiver, accelerometer and electrodes are simple on the outside; shaped like a small, sleek mobile phone. Inside they are a mix of an insert-mold and over-mold, attachment, and shock-absorption detail.



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Sotera Wireless is a start-up funded by Qualcomm Ventures, Intel Capital, Sanderling Ventures, and Apposite Capital. Having a relationship formed by intensely focused parties is always the best kind of product development, as the goal is getting the product to market. The ViSi Mobile system gained FDA clearance in early 2012.

DD STUDIO engaged in ethnographic research, furthered user feedback loops, completed the industrial design and mechanical engineering, and provided our deep relationships with toolmakers and molders to ensure the success of the ViSi Mobile project.



Images: **2** - Continuous vital signs monitoring keeps clinicians connected to their patients whether in transport, in the emergency room or in general inpatient units. **3** - Featuring comfortable body-worn sensors that allow for freedom of movement and the capture of multiple vital-signs, the technology also enables continuous accurate blood pressure measurement for ambulatory patients without the need for frequent cuff inflation. **4** - "Wireless monitoring of blood pressure holds great promise to change the landscape, and will be particularly helpful for dealing with labile, sporadic surges in blood pressure that are currently undetected. Furthermore, the ability to have continuous hemodynamic assessment of individuals will provide a new window for better management and hopefully, ultimately, improvement in major outcomes." Eric Topol, MD

