



## FDA Approves Mobile App for Managing Diabetes

Patrick Totty  
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The U.S. Food and Drug Administration has cleared Baltimore-based health software company WellDoc to begin marketing the DiabetesManager® System, a mobile phone application designed for patients and healthcare providers who are dealing with type 2 diabetes. The company, founded in 2005, plans to start selling the product early next year.

DiabetesManager collects real-time data on blood sugar levels, then analyzes it for trends. If an app user is, for example, trending low, a built-in program delivers advice to correct the low reading as soon as possible. The app also delivers other lifestyle tips designed to remind the user how to manage type 2 in a consistent way.



Users' data and data analyses are also sent to their healthcare providers. The ability to send and receive data via mobile phones or the Internet allows patients' doctors to track them remotely and respond without having to schedule physical office appointments.

Externally, the data also goes through WellDoc's proprietary Automated Expert Analytics System, which analyzes it for trends and delivers educational and coaching tips tailored to the individual app user. Users' data and data analyses are also sent to their healthcare providers.

WellDoc is testing DiabetesManager in several pilot programs, including one with the U.S. Air Force and another with Jitterbug phones, a mobile phone provider noted for its low rates, easy-to-use equipment, and focus on the needs of seniors.

Before it can begin actual U.S. sales, WellDoc has several FDA audits ahead of it. The agency will be monitoring the system's performance as well as its manufacture. Certification and success in the U.S. market will assure a good reception to the product overseas, especially in parts of Asia, Europe, and the Middle East, where the incidence of type 2 is approaching epidemic proportions.