



US 20060084848A1

(19) **United States**

(12) **Patent Application Publication**
Mitchnick

(10) **Pub. No.: US 2006/0084848 A1**

(43) **Pub. Date: Apr. 20, 2006**

(54) **APPARATUS AND METHODS FOR MONITORING SUBJECTS**

(52) **U.S. Cl. 600/301; 600/549; 128/903; 600/595; 600/591; 600/573**

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(57) **ABSTRACT**

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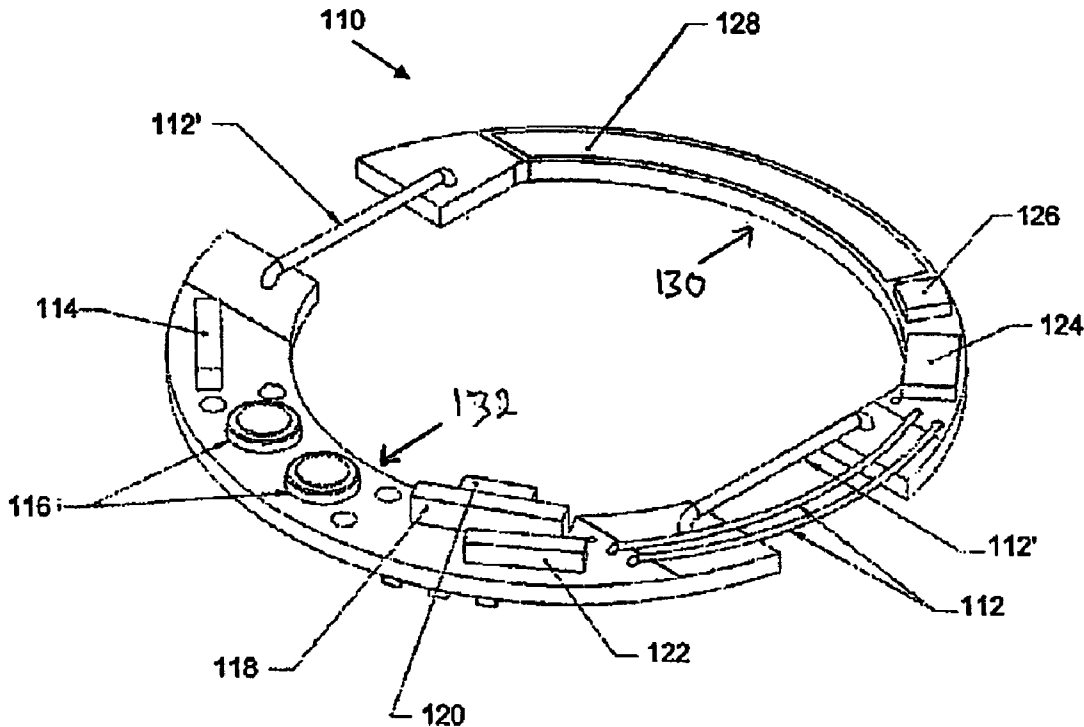
This invention provides a device, and method and system for its use, for monitoring participants in clinical trials so that participant self-reporting, which is known to be notoriously inaccurate, can be minimized or eliminated. In preferred embodiments, the device is self-contained and self-powered, resides on or in a body cavity of the participant, collects data monitoring medically relevant aspects of the participant's behavior and of the local device environment, and stores data in a memory on-board the device. An accompanying external station reads stored data and prepares it for use. Devices may include electrically-active sensors and non-electrical active sampling sensors. A preferred embodiment of the device is in clinical trials of microbicides inhibiting transmission of the HIV virus.

(21) **Appl. No.: 10/965,010**

(22) **Filed: Oct. 14, 2004**

Publication Classification

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/103 (2006.01)



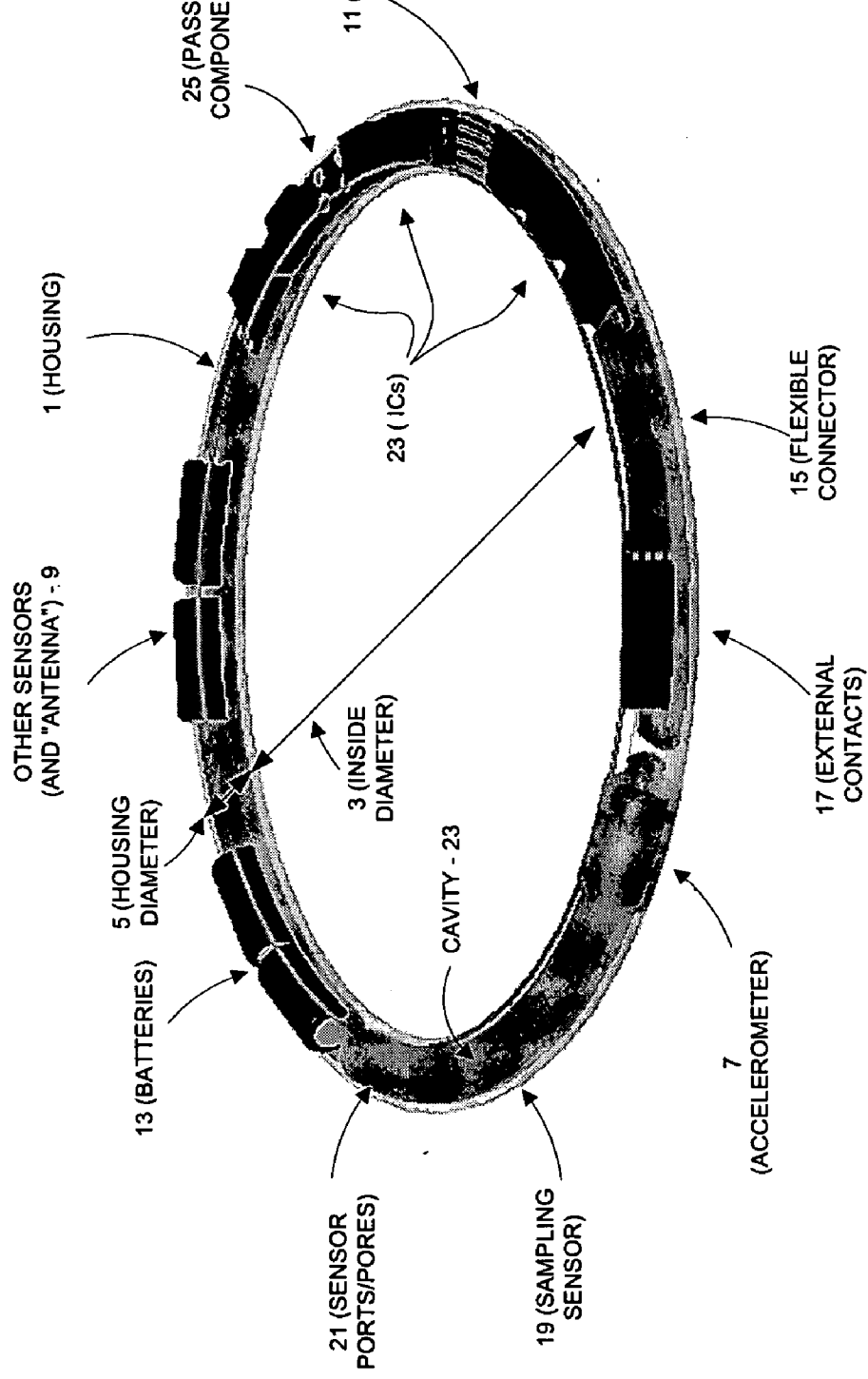


FIG. 1

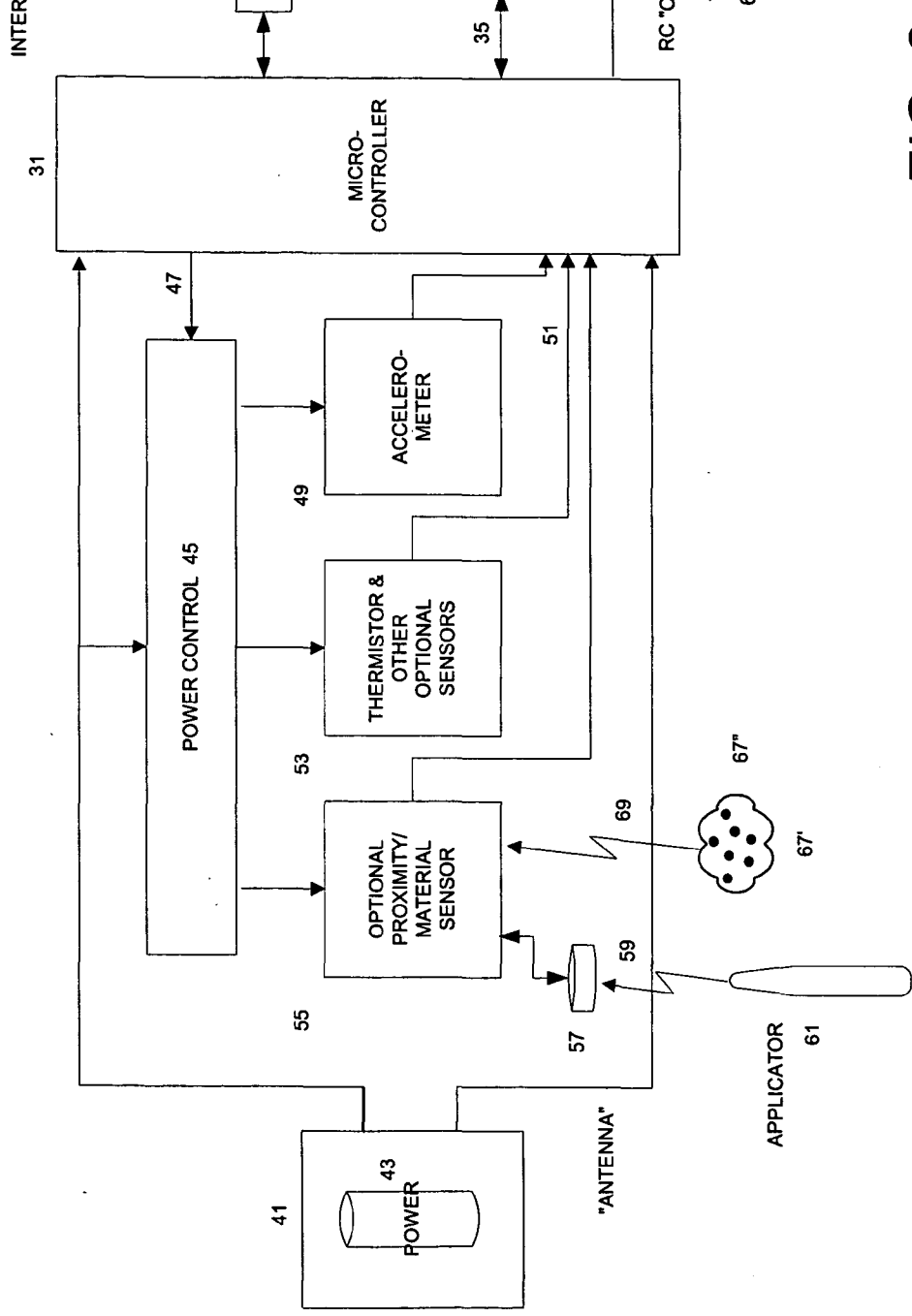


FIG. 2

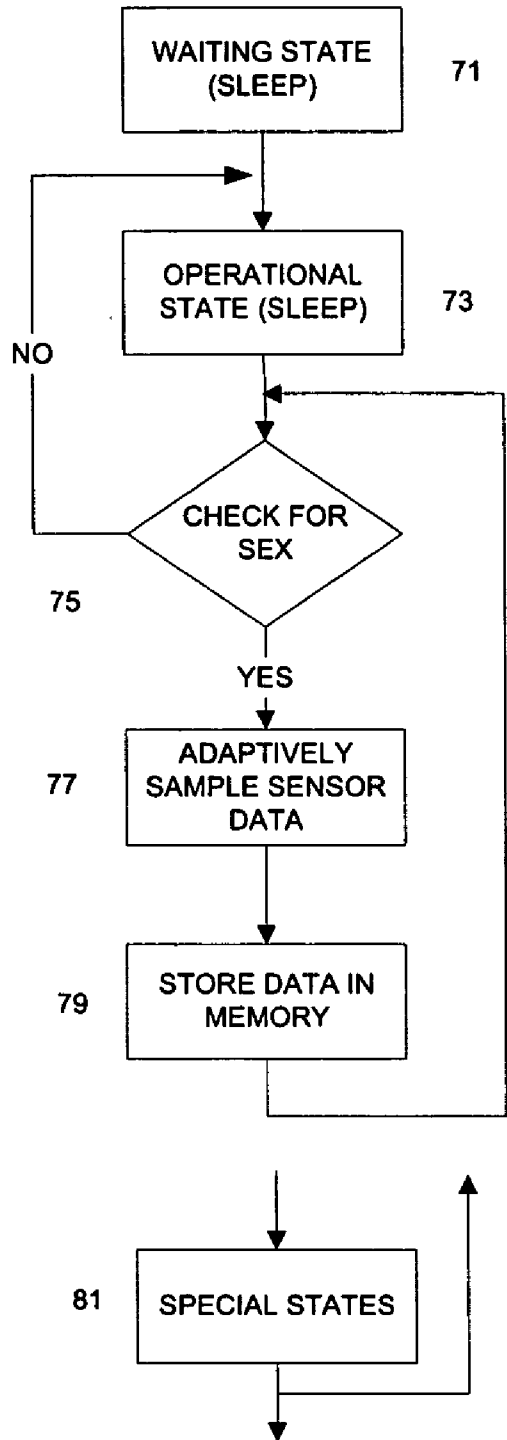


FIG. 3

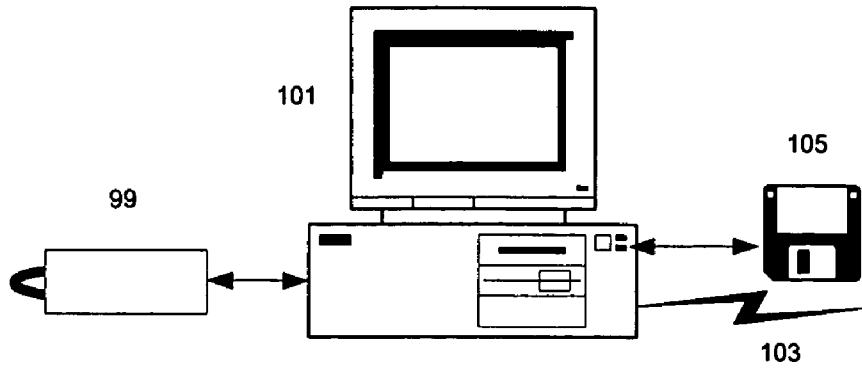


FIG. 4A

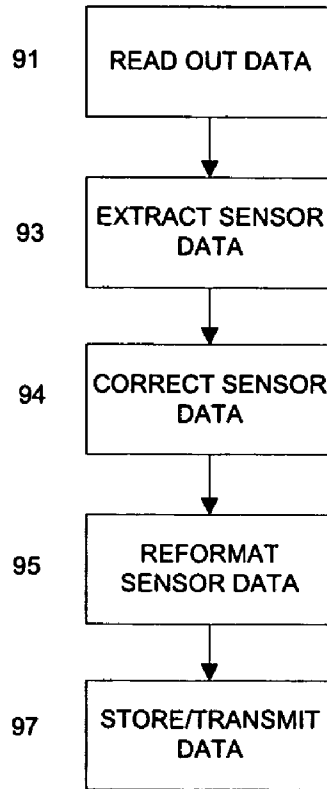


FIG. 4B

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