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

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(76) **Inventor: Mark Mitchnick, East Hampton, NY (US)**

(57) **ABSTRACT**

Correspondence Address:  
**Dwight H. Renfrew, Esq.**  
**Ohlandt, Greeley, Ruggiero & Perle, L.L.P.**  
**10th Floor**  
**One Landmark Square**  
**Stamford, CT 06901-2682 (US)**

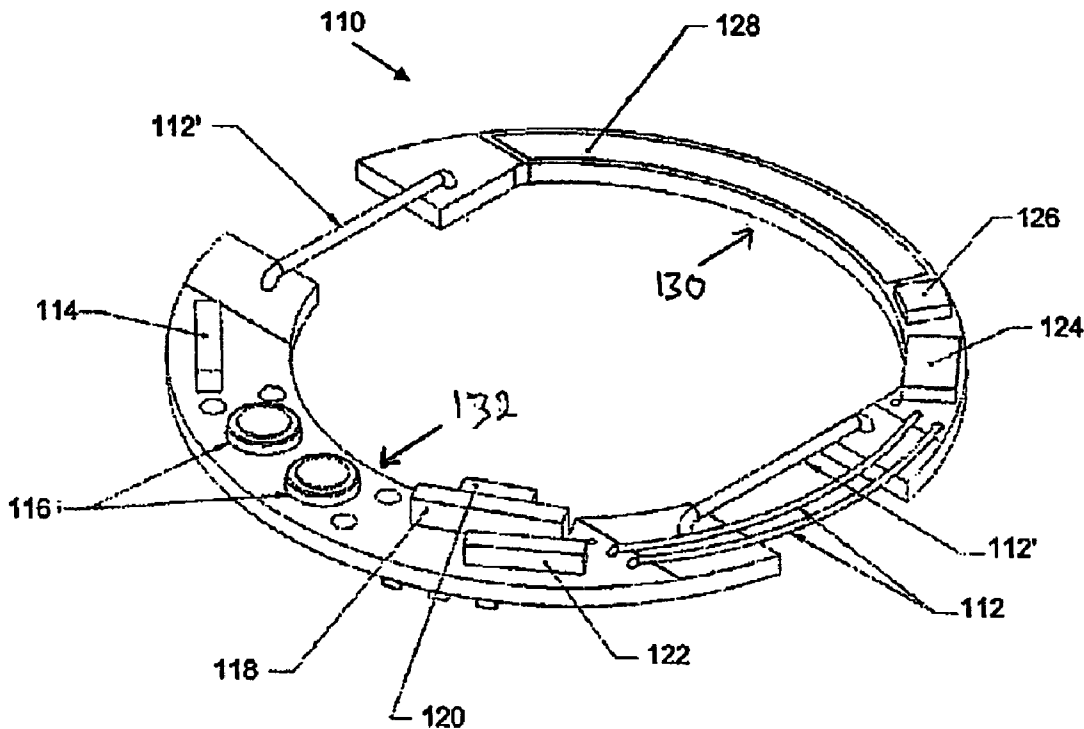
This invention provides a device, and method and system for its use, for monitoring participants in clinical trials so that participant self-reporting, which is known to be notoriously inaccurate, can be minimized or eliminated. In preferred embodiments, the device is self-contained and self-powered, 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.

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**A61B 5/103 (2006.01)**



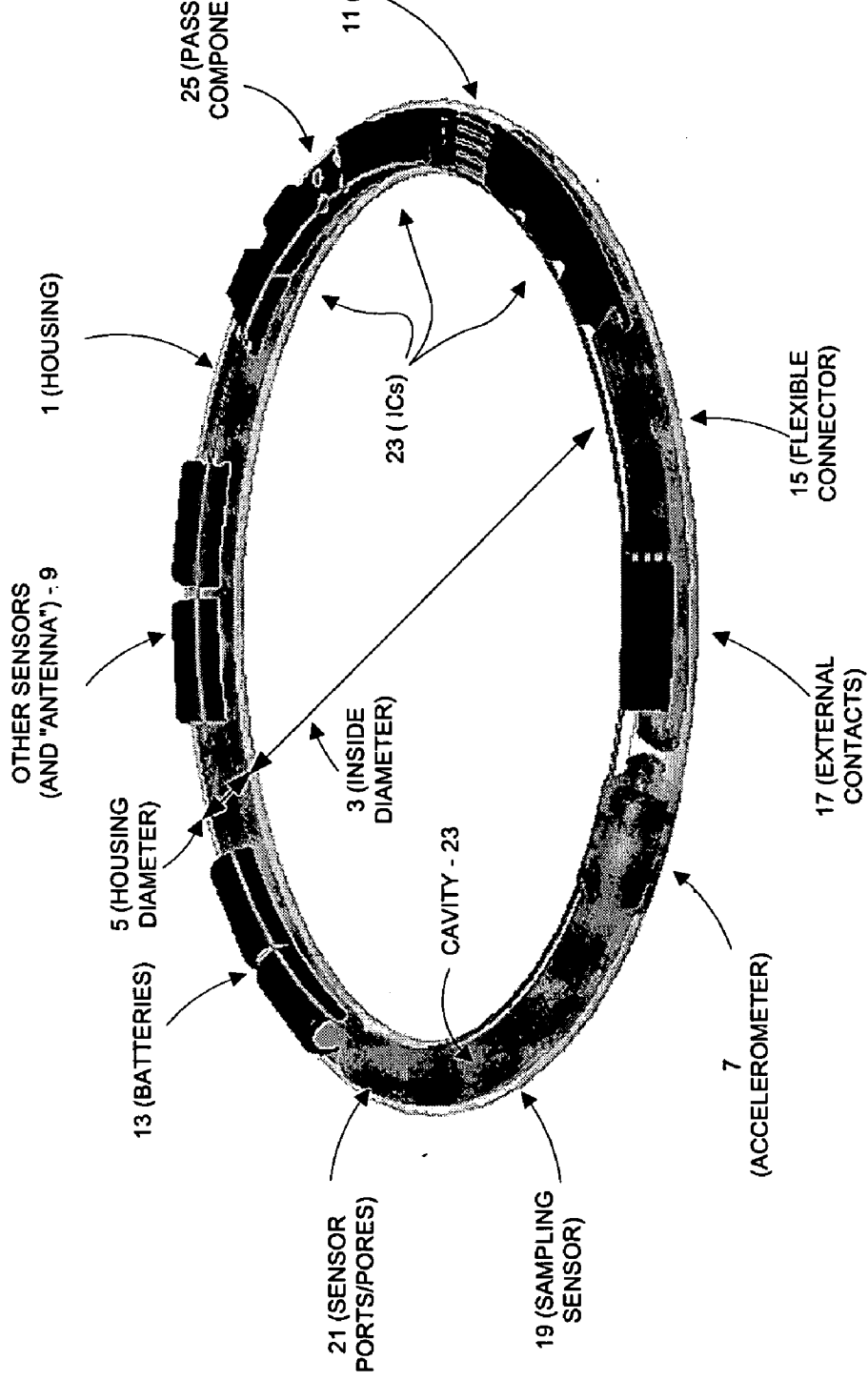


FIG. 1

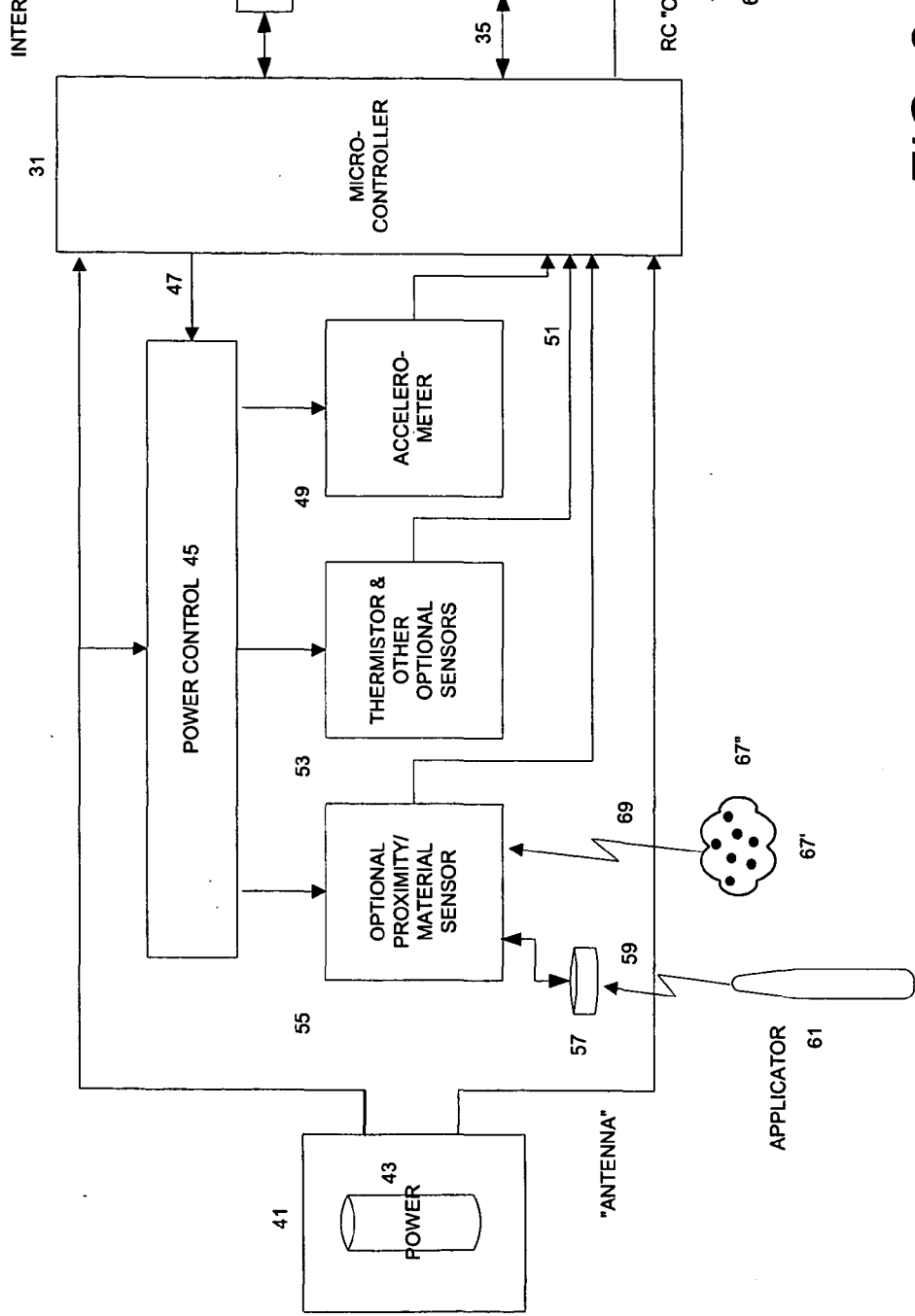


FIG. 2

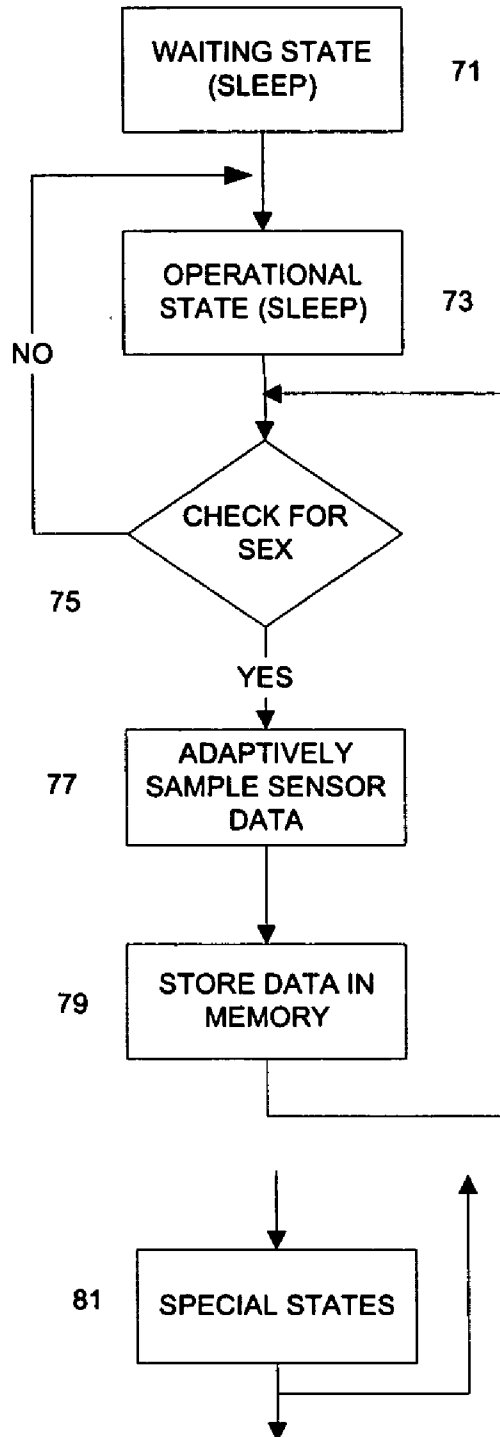


FIG. 3

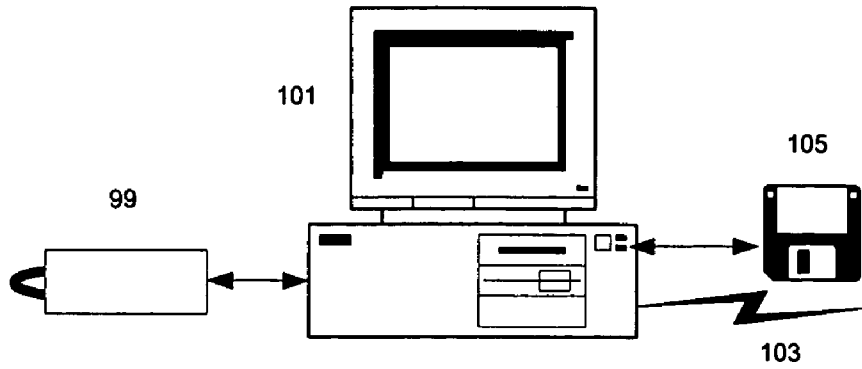


FIG. 4A

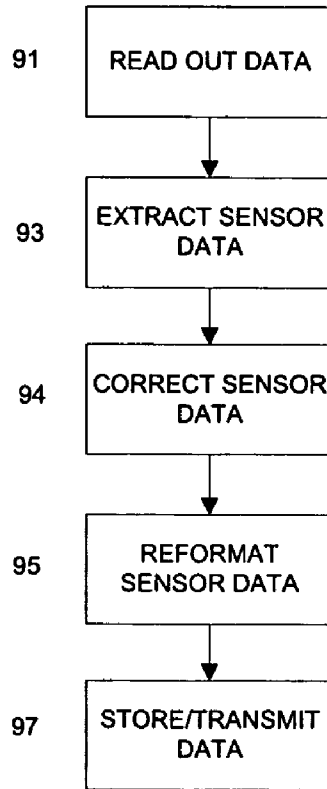


FIG. 4B

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