Portable system for pre-cancer screening at point of care

Country of origin | United States of America

Health problem addressed

Today, more than 70% of the world’s cancer deaths occur in developing countries, where more than 80% of patients present with advanced disease at the time of diagnosis. Advanced imaging tools are generally only available at regional centers in industrialized countries; in low- and middle-income countries, most diagnoses are based on clinical signs and symptoms. There is a demand for objective point-of-care cancer screening tools.

Product description

The device is a portable, battery-powered system to screen for pre-cancer at the point of care. The device is essentially a wide-field epi-fluorescence microscope coupled with a flexible fiber-optic imaging bundle (1 mm in diameter) that can identify the differences between normal and pre-cancerous epithelial tissues in situ.

Product functionality

After applying a fluorescent dye to the tissue to be imaged, the tip of a flexible fiber-optic bundle is placed on the tissue. Light emitted from the tissue returns through the same fiber and is imaged onto a digital camera. Images of cellular detail can be viewed in real-time on a computer screen and interpreted by a trained user for diagnosis.

Developer’s claims of product benefits

In high-income countries, cytology or biopsy collection followed by histopathology processing is used to diagnose, and, in some cases, screen for disease. The process involves sampling, sectioning and staining tissue specimens prior to microscopic evaluation, which is highly resource intensive and provides diagnostic information at a single location and point in time. The high resolution microendoscope integrates in vivo microscopy and optical labelling to provide anatomical and functional indications of disease, enabling similar cellular-level diagnostic information to be acquired without the need to remove and process the specimen, and streamlining the process of diagnosis. Using the microendoscope is cost-effective and has the potential to diagnose cancer in its early stages. Additionally, the device is portable and battery-powered.

Operating steps

A contrast agent is applied to the tissue site. The fiber-optic probe is placed on the site to obtain images of the cellular morphology. The images are presented on a computer screen in real time and interpreted by a trained user. The fiber optic probe is disinfected between each patient.

Development stage

Technical aspects of the product have been evaluated in the laboratory. Preliminary field testing of prototype versions of the product has been conducted in the US, China, Guatemala, and Botswana, establishing feasibility of the technique. In vivo cervical imaging studies have involved over 250 patients to-date, with microendoscope images and biopsies acquired at sites considered to be normal and abnormal by expert visual impression. Current evaluation of data from these sites aims to establish the diagnostic accuracy of the device relative to biopsy. Results are not yet available. The current version of the device is an advanced prototype. A patent is pending.

Future work and challenges

To make this technology available in the developing world, we need to secure the appropriate regulatory approval, and identify financing, manufacturing, and distribution partners. Depending on the site of the cancer, barriers to cultural and social acceptability would be similar to those associated with a standard gynecological exam.

Use and maintenance

User: Physician, technician

Training: Medical personnel experienced in cancer screening techniques will need additional training in interpreting the images to form a diagnosis. Personnel would also need training in proper cleaning and sterilization of fiber-optic probe end.

Maintenance: Technician, engineer

Environment of use

Requirements: The microendoscope can operate under existing infrastructure constraints. It is powered by a single 12V rechargeable battery for up to 6 hours. It requires connection to a laptop, personnel trained to interpret the images for diagnosis, and a method to sterilize the fiber optic probe.

Product specifications

Dimensions (mm): 254 x 203.2 x 50.8

Weight (kg): 2.27

Consumables: Contrast agents; cleaning supplies for fiber optic probe.

Other features: Portable and reusable. Runs on batteries, uses software, and is compatible with telemedicine systems.

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