# Colposcope for visualization of cervical cancer, mobile

Country of origin | Israel

Primary function | Diagnosis

## Health problem addressed

Cervical cancer is the leading cause of cancer death for women in low-resource settings, with 528 000 new cases each year that result in 266 000 deaths. In contrast to low- and middle-income countries, cervical cancer rates in member countries of the Organisation for Economic Co-operation and Development (OECD) have declined drastically since the implementation of regular Pap screening 50 years ago. However, Pap testing requires a clinical workforce and laboratory infrastructure that is lacking in in many LMICs, and as a result, patients do not have this access to screening.

## Disease addressed

Certain infectious and parasitic diseases; neoplasms; diseases of the genitourinary system; injury, poisoning and certain other consequences of external causes.

## Technical descriptions

This system enables enhanced visual inspection of the cervix, allowing nurses and doctors to perform visual inspection with acetic acid (VIA) with magnification, polarization to reduce glare, and a consistent light source. The system securely captures cervical images and patient information to be used for improved patient tracking, follow up and referral, and allows for continuing medical education and ongoing supervision of screeners.

## Developer's claims of products benefits

In 70 LMICs around the world, cervical cancer screening is done by VIA, an easy to implement procedure with limited diagnostic accuracy. To perform VIA, a practitioner applies a thin layer of 3-5% acetic acid to the cervix and visualises it from outside the vaginal canal using a light source. However, VIA suffers from a positive predictive value (PPV) of only 17%. This leads to overtreatment, and costs under-resourced health systems money, equipment, and time. This technology can be used to visualise the cervix to conduct VIA.

## Operating steps

Turn on the phone. Enter the application using a password. Enter the patient information. Examine the patient using the lightsource on the device to visualise the cervix in the phone. Images can also be captured for later review, for patient sensitization and for remote consultation. The data is automatically stored in a cloud.

## Regulatory status and standards compliance

Ministry of Health Pharmacy and Poisons Board, Kenya. IEC 60601 ISO 8600 series. (ISO 8600-5 and ISO 8600-3, respectively).

## Use and maintenance

**User:** Midwife, nurse, general physician, specialised physician (gynecologist).

**Training:** The materials necessary for the training are the visualisation device and a smartphone with the dedicated mobile phone application. The training is focused on entering patient information, visualising the cervix, capturing images, entering a decision, marking a case for consultation, using the online webportal, maintenance and troubleshooting. Depending on the comfort level of the healthcare provider with a smartphone, the training can take anywhere from 1-4 hours.

**Maintenance/Calibration required:** No

## Environment of use

**Setting:** Rural settings, urban settings, outdoors, indoors, primary level (health post, health centre), secondary level (general hospital), tertiary level (specialists hospital), ambulances, screening camps.

**Energy requirements:** Rechargeable battery.

## Product specifications

**Weight (kg):** 1

**Dimensions:** 208mm x 78mm x 110mm

**General product:** Speculum, acetic acid, gloves

**Lifetime:** 10-15 years

**In UN catalog:** No

## Commercial information

**Reference price (USD):** $1'500.00

**Year of commercialization:** 2014

**Number of units distributed:** 101-1 000

**Software requirements:** Proprietary

**Model:** Enhanced Visual Assessment (EVA) System, with CervDx mobile phone application

**Other features:** Portable, reusable (assuming appropriate decontamination and/or other reprocessing between uses)

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