

Enhanced Visual Assessment System

EVA System – Hardware Guide

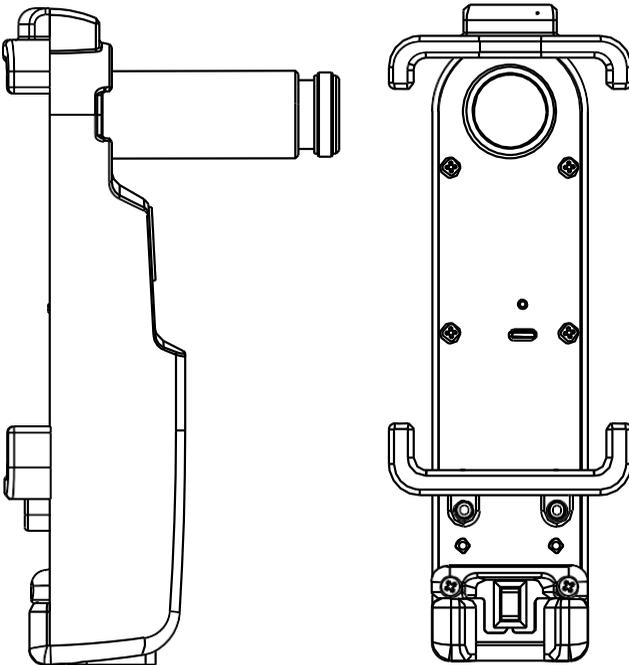


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Doc. 10-GE-002	Rev.01	Printed on 29/06/2016
Mobile ODT, LTD Gershon Shatz 41 2nd Floor Tel-Aviv, Israel.		

Welcome to the EVA (Enhanced Visual Assessment) System

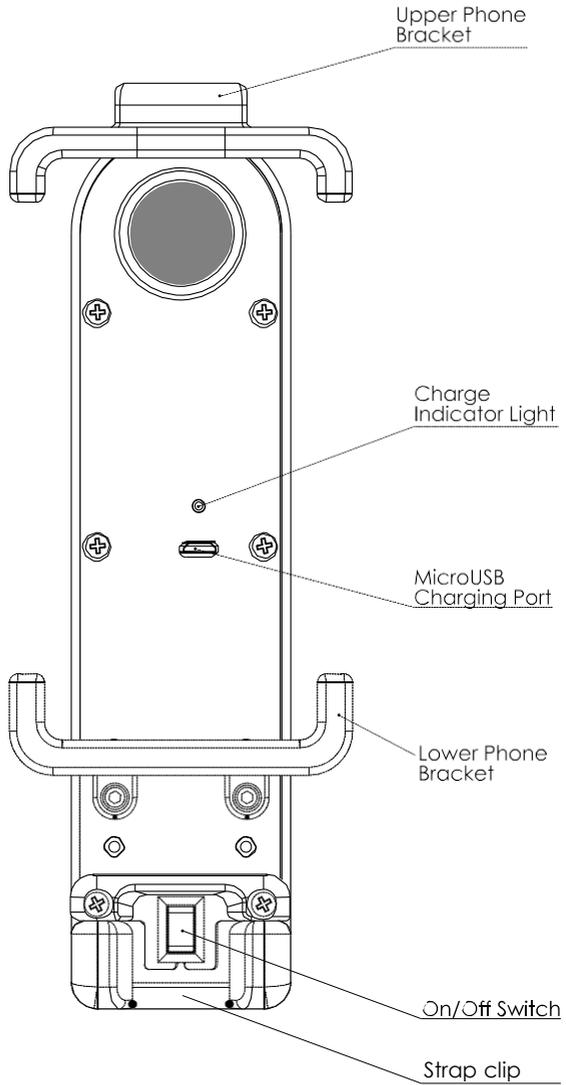
Thank you for choosing to use the EVA System. The System has been developed for use by health providers to enable a more powerful visual examination. The EVA System is intended to provide magnified views of the vagina, cervix and external genitalia in order to aid in detecting abnormalities and guiding treatment.

In the following pages you will learn how to use the EVA System and its different components. The current version of the EVA System is a result of rigorous research, testing and ongoing learning from use in the field. We are constantly looking for new and exciting ways to improve the System and support health providers. Please do not hesitate to reach out to support@mobileodt.com with any idea, question or thought you may have!

We are proud that The EVA System is currently deployed in over 20 countries around the world, supporting the work of health providers in hospitals, doctor's offices, rural clinics, screening camps and more. Wherever you are using the System - we are excited to support you in providing the best and most effective care for your patients.

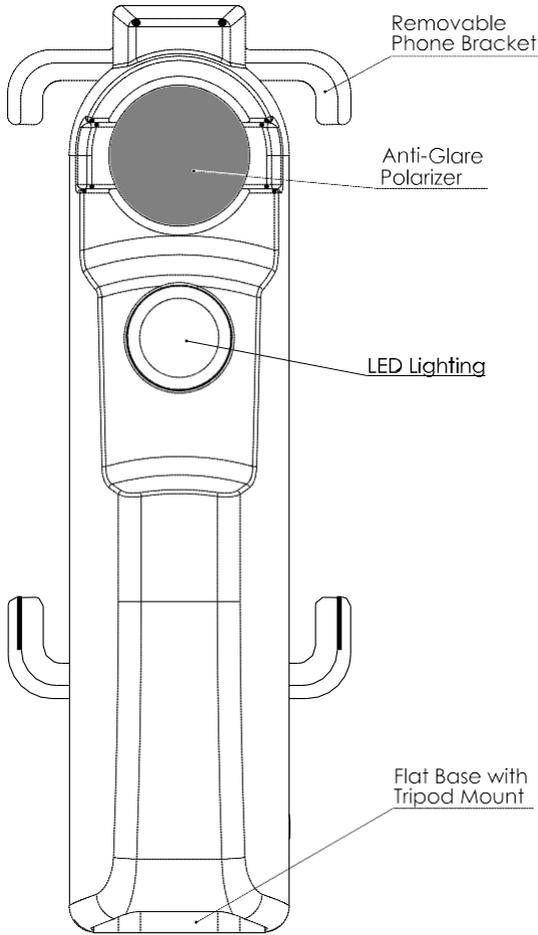
All the best,
Your friends at MobileODT, Ltd

EVA System: User Guide
Get to know the EVA System

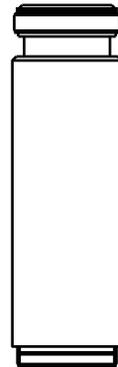


Back View

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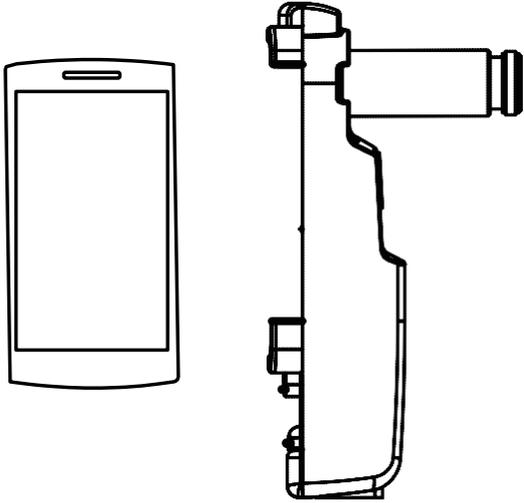
Front View



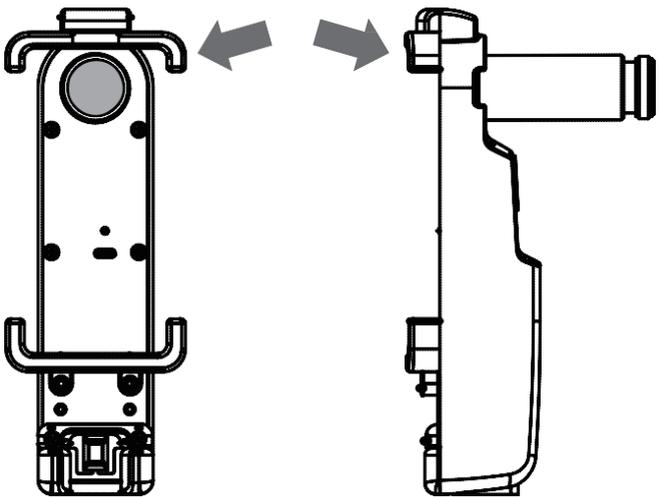
Lens

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Assemble the hardware

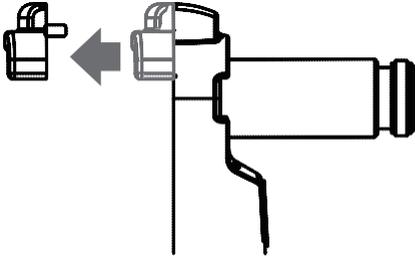
1. Take out items



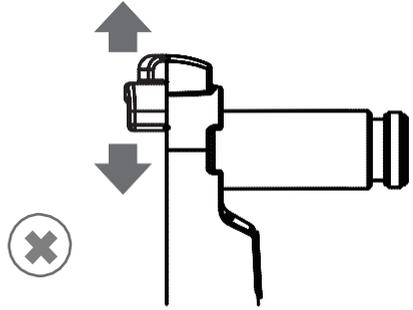
2. Top bracket



3. Pull bracket outward

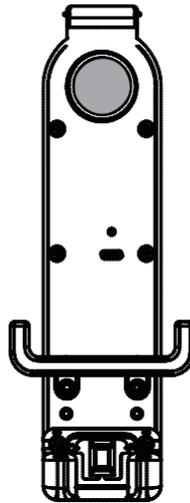
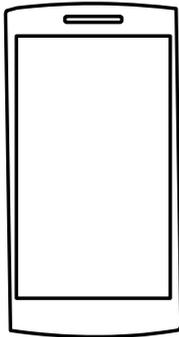


The bracket is magnetic.
Apply gentle force.

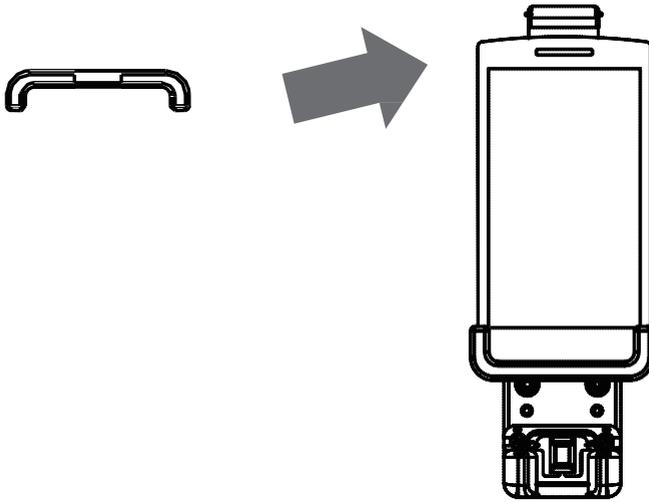


Do not pull up or down.

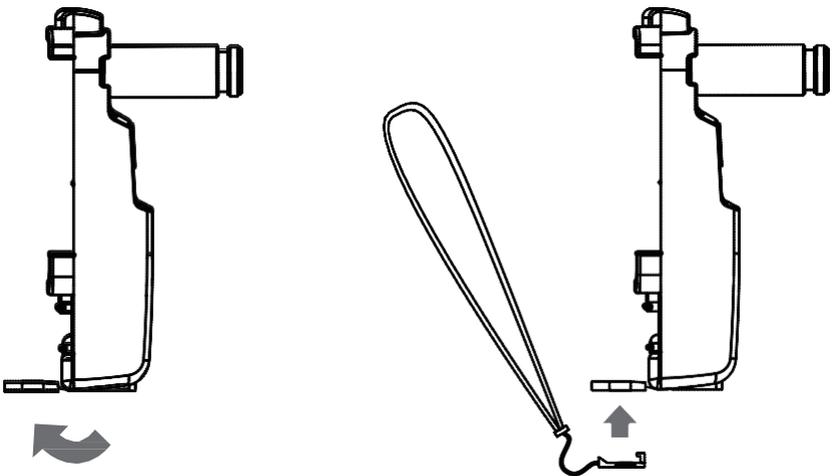
4. Place phone into the device



5. Connect bracket to device

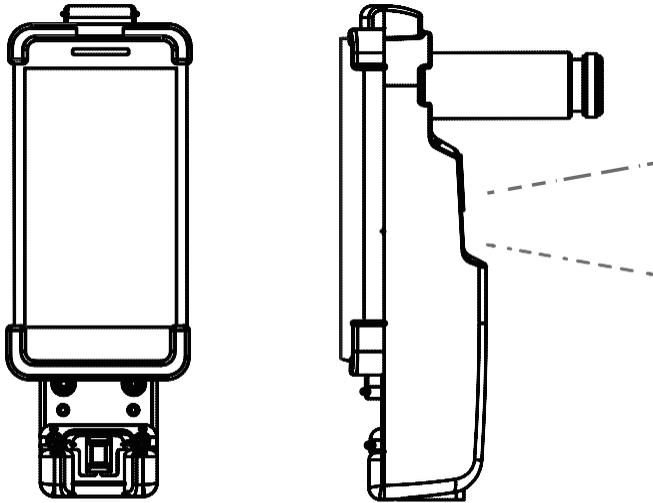


6. Attach the strap to the bottom of the device

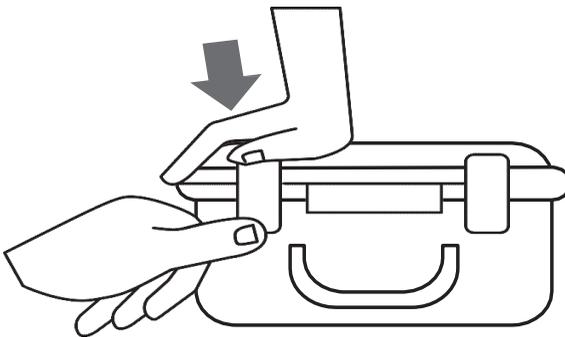


The latch on the strap fits into the latch on the device.

7. The device is ready for use



8. After the examination, be sure to store the EVA System in the storage box. To close the box push downward on the corner of the case and lock the two latches.



9. In order to use the EVA System, it is necessary to install the designated software on the smartphone. Please refer to the software handbook provided for further information. If you did not receive such a handbook, please contact support@mobileodt.com for further assistance.

How to capture clinically-useful image?

Clinically images are critical for remote consultation, documentation and quality assurance. There are five simple ways that make sure an image is clinically-useful:

Stability

The EVA System Device should be held in a stable position while capturing an image. The Device can be stabilized by:

1. Using the neck-strap: when holding the Device by hand and neck-strap, please confirm that the neck-strap is completely out-stretched. The length of the neck-strap can be adjusted for the user's comfort.



Aside from the neck-strap provided with the System, there are several other ways to stabilize the device:

2. Using a tri-pod: The EVA System can be attached to any standard camera tri-pod. The height of the tri-pod should match that of the examination table (standard medical table height is 80-110 cm).
3. Foot pedal: The EVA System can connect to any standard Bluetooth foot pedal, which allows the user to perform the examination without touching the smartphone's screen, reducing vibration that may lead to motion blur and compromised image quality.
4. Hand Gestures: Images can be captured without touching the screen, through the "hand gesture" feature. If this feature is activated when the user waves in front of the screen while in the visualization screen, the EVA System will capture an image.

Please note that options 3 and 4 are only available to those users who are using a tri-pod or stand together with the System.

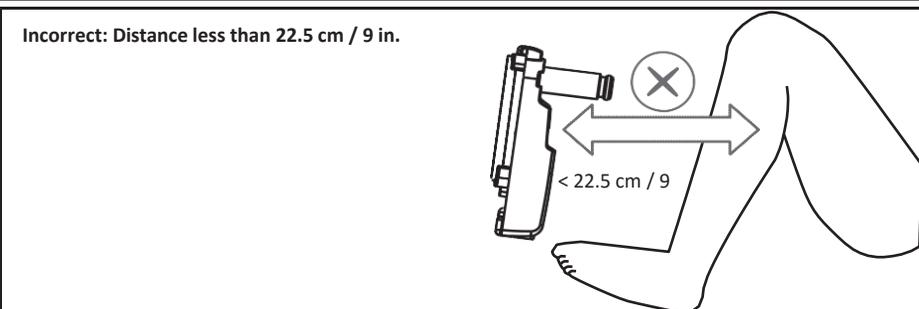
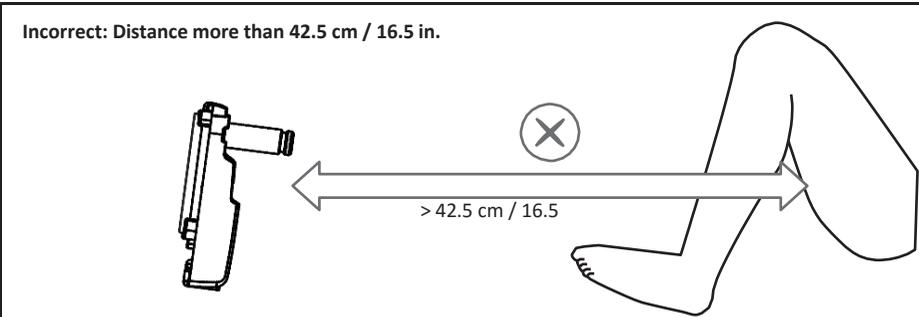
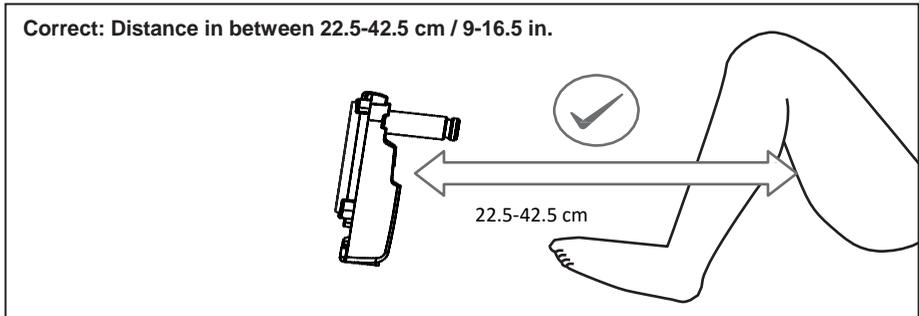
MobileODT can provide a designated stand on which the device can be mounted, as well as a foot-pedal that has been tested to work with the EVA System. For further information, please visit www.mobileodt.com or contact support@mobileodt.com.

Positioning

1. **Distance:** The device should be positioned at a distance of 22.5-42.5 cm / 9-16.5 inches from the patient's vaginal canal.

Important: the device should not come into physical contact with the patient.

2. **Angle:** The entire face of the cervix should be captured in the image, without the speculum. The lens of the device is aimed directly at the patient's cervix.

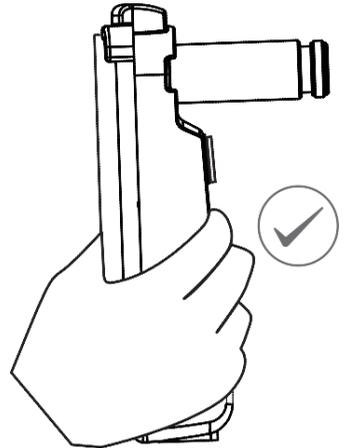


Light

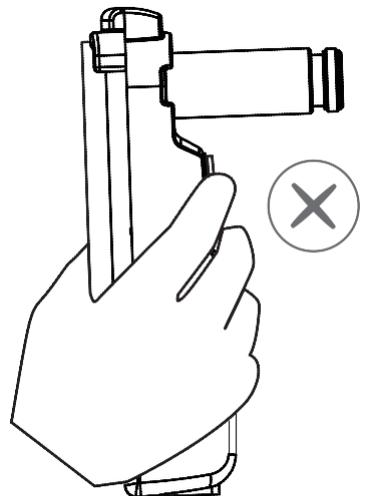
The cervix should be fully illuminated and without glare.

1. The EVA System reduces glare with a filter, however glare from the speculum is still possible. If this is the case, reposition the EVA System and/or the speculum until there is less glare.
2. When holding the device, do not block the light-source with your finger.

Correct: Hand is not blocking light-source.



Incorrect: Hand is blocking light source.

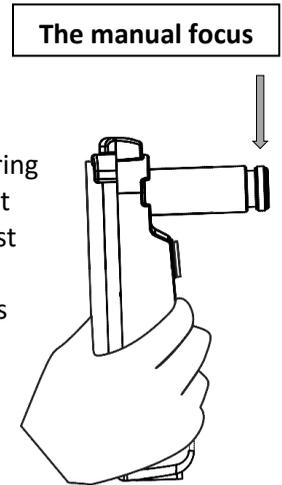


Focus

There are two ways to adjust the focus of the EVA System. The first is to adjust the distance between the device and the patient. Remember that the position of each cervix is different, so it may be necessary to readjust your position according to the patient to ensure the EVA System remains in focus.

Once you have achieved adequate focus, as you zoom in and out digitally you can use the manual focus wheel at the tip of the lens to adjust your focus.

The recommended default setting for the manual focus ring is having it turned completely to the right. If you find that working at the distance which normally yields the clearest images doesn't work, you can try adjusting the focus manually by turning the focus wheel at the tip of the lens to the right and to the left.



After you have captured images, it is important to review the images captured to verify that they are clinically-useful.

Care and Maintenance

Taking care of the EVA System is simple - no great effort is needed to keep it in a tidy and functional condition. We recommend that you consistently carry out the measures described below, in order to ensure long-term and trouble-free functioning.

- **Storage:** For the protection of the entire System and, in particular, the optical system, we recommend placing the device in its provided case when not in use, in order to minimize dust contamination of the device.
- **Liquids:** liquid splashes on the front panel can occur with device usage and these should be wiped off. If the external optics are soiled, they should only be cleaned with commercially available lens cleaning papers or moist spectacle cleaning cloths Do not use towels.
- **Disinfecting:** Lugol's solution will damage the enamel finish and is very difficult to remove. Moisten a cloth with diluted alcohol and wipe the enamel to remove Lugol's. Standard detergents can also be employed with the usual dilution.

Please do not use strong detergents or concentrated alcohol under any circumstances for the cleaning of optics. This would lead to irrevocable damage to the optically coated lens surfaces.

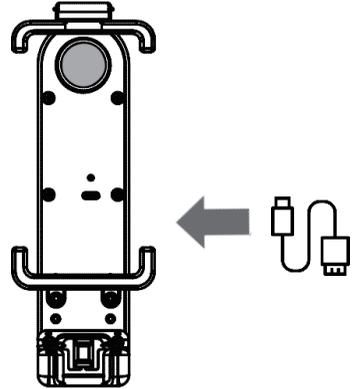
Charging

Charging the device

The EVA System's light source is powered by a rechargeable battery contained within the device. The battery possess charge capacity sufficient for approximately 10 hours of continual or intermittent use.

To charge the EVA System, simply remove the phone from the device and connect the USB charger into charging port found on the back of the EVA System. Connect the cable to the wall with the proper USB-electrical port adapter.

Please note: such adapters are not provided with the EVA System, as they vary greatly from country to country.



A LED indicator light resides above the charging port on the back of the device. When connected to the charger, the light will turn on and turn green when fully charged.



WARNING: The device should not be used while it is being charged.



WARNING: If the LED Illumination Light ceases to work, due to battery drain or bulb burn out, stop using the device and recharge the batteries. Sometimes a discharged battery will manifest itself by blinking the LED very rapidly. In this case, recharge the battery to full capacity before continuing use.

Charging the phone

Charging of the phone should be done according to the instructions provided in the phone's user manual. The phone should be charged whenever the EVA System is not in use in order to ensure proper functionality during the examination.

In case the device and/or smartphone have been stolen, please contact support@mobileodt.com immediately.

Device Troubleshooting

- **LED won't turn on**

If the LED won't turn on, make sure the EVA System is fully charged. If, after charging, the LED does not turn on, the user should contact service.

- **Low Battery**

If low battery or depleted battery is suspected, the user should check that the Illumination LED is lit. If it is not lit, the user should charge the battery.

- **Battery Disconnection**

If the battery becomes partially or fully disconnected the user should contact service. If your EVA System is fully charged but the LED illumination is not turning on, or turning on and off, this may indicate battery disconnection.

Warning: This device contains lithium batteries. A battery replacement by inadequately trained personnel could result in a hazard (such as excessive temperatures, fire or explosion).

- **Illumination LED Lights**

If the user suspects that the Illumination LED is burned causing artifacts in the image or a low-resolution image, the user should check that the Illumination LED is lit. If it is not lit and the battery is charged, the user should contact service to replace the device.

- **LED Indicator Lights**

The user should check that the LED indicator light is lit during battery charge. If it is not lit, it may indicate that the light has burnt out and the user should contact service to replace the device.

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- **Brackets**

If the device brackets are broken and the smartphone is not sitting properly in the cradle causing artifacts in the image or a low-resolution image, the user should contact service to replace the device.

- **Device Casing**

If the device casing is cracked or not intact leading to artifacts in the image or low-resolution image, the user should contact service to replace the device.

- **On/Off Switch**

If the on/off switch is stuck in either the on or off position, the user should contact service to replace the device.

- **USB Connector**

If the USB connector (input) is broken, the user should contact service to replace the device.

Lens Troubleshooting

- **Lens Cracks or Misalignment**

If there are artifacts or low-resolution images because of a cracked or misaligned lens, the app's software should check for distortions in the image or the user should do a calibration check daily. If either of these checks fail, the user should contact service to replace the lens.

- **Dirt on Lens**

If there are artifacts or low-resolution images due to dirt on the lens, the app's software should check for distortions in the image or the user should do a calibration check daily. The user should also clean the lens. If these checks fail, the user should contact service to replace the lens.

- **Focus Adjustment**

Focus is maintained with the colposcope by adjusting the separation of the objective lens, positioned at the far-end of the lens tube opposite the smartphone's camera, from the rest of the lens system. This can be done by screwing the end piece in or out. The two extreme positions correspond to working distances of 22.5 and 42.5cm.

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Replacement Wear Parts and Technical Service

When contacting MobileODT's Service and Repair department for servicing the EVA System, you will need to provide the following information: Details on the defect that has occurred and corresponding serial number of the device. These can be read off from the label located on the back of your device, where the phone is to be inserted.

For questions concerning service, please contact us at support@mobileodt.com

The following is the contact information for MobileODT, the manufacturer of the EVA System:



MobileODT, LTD. Gershon Shatz 41 Tel Aviv, Israel
support@mobileodt.com Phone: +1-(617) 454-4687
Website: www.mobileodt.com



The following is the contact information for the Authorized Representative used for this device:

MedNet GmbH Borkstrasse 10
48163 Muenster, Germany www.medneteurope.com



Technical Product Overview

Before initial set up of the EVA System, check for damage on the outside of the transport packaging, the device, and any accessories. Please check all components received against the parts list of components section to verify a complete set. If parts are missing, please notify MobileODT. The EVA System always includes the following items:

1. The colposcope body
2. The lens
3. The upper and lower phone brackets*
4. The neck strap: provided to aid with the usability of the device, for ease of carrying and for use as a supplementary fulcrum. It can support the weight of the colposcope while the user uses his or her hands for other aspects of providing care and it can be used as a support to help stabilize the camera while it is being held by the user's hands.
5. The mobile application
6. The web portal
7. User guide

*The device does not include the Smartphone. Phones that are compatible with this device include the Moto G2, Moto G3 and Samsung J5.

Illumination

Illumination of the EVA System is provided through a LED light-source found on the body of the device. It has been designed to transmit no heat or electricity, and to be comfortable for touch during a normal, 10-minute session. It includes:

- Three 16850 LiOn 2600Mh batteries + protection circuit.
- Two 350 mA LED drivers (700 mA)
- ON/OFF switch
- Micro USB charging circuit 5V input (1.5A - 2A Max)

The 3W LED is operated at 2.5W providing ~230 Lux of luminous flux at a beam angle of 15 degrees.

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Specifications

Item	Specification	Technical Data
Power Requirements	Charger Input Voltage Frequency Output	As rated by MicroUSB Charger As rated by MicroUSB Charger 5V DC
Dimensions	Colposcope (HxWxD) Lens	20.8cm x 7.8cm x 11cm (w/lens) 20.8cm x 7.8cm x 6cm (w/o lens) 93.1mm long x 30mm diameter
Weight	Colposcope Lens	400g 108g
EVA System Specifications (For Samsung J5)	Working Distance Magnification Field of View Depth of Field	225mm – 425mm 4.0X optical/17X with digital zoom (at 250mm) 3.8X optical/16X with digital zoom (at 450mm) 54mm (at 250mm) - 106mm (at 450mm) 17mm (at 250mm) - 34mm (at 450mm)
Operating Environment	Ambient Temperature Relative Humidity Atmospheric Pressure	50°F (10°C) to 105°F (40°C) 95% max 70kPa to 110kPa
Illumination	Lamp type Lamp voltage	6500K 3W LED 3.6V

Appropriate Use

Indications for Use

The EVA System is intended to provide magnified viewing of the vagina, cervix and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The device is intended for use in hospitals, doctors' offices, and remote and rural clinics.

Contraindications

There are no contraindications for use of the EVA System.

Risks and Benefits

The EVA System should not touch the patient, and thus does not present any risk to the patient. The system has been tested according to specific medical standards.

Important Notes on Safety

Before you begin using the colposcope, please become familiar with the following safety regulations and keep these in mind while using the device:

Users of the EVA System should be thoroughly trained in the appropriate medical procedures. DO take the time to read and understand these instructions before performing any procedure.



List of Warnings

1. Local and/or other applicable laws may restrict the sale of this device to, or to the order of, a physician or other appropriately licensed medical professional. This EVA System may not be used unless you or your organization meet the requirements and/or obligation under such laws and you assume full responsibility for any illegal purchase and/or use of the device. The EVA System should only be used by a trained and licensed operator, whose accreditation is valid in the country and/or region in which the procedures are being conducted.
2. The EVA System was built to be resilient, but should be used as you would use your mobile phone. It should never be stored or operated in areas where it could get wet or could be exposed to environmental conditions such as extreme temperature or humidity, prolonged direct sunlight, dust,

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etc.

3. All service to the EVA System must be performed by MobileODT or by an authorized repair center.
4. There are no user serviceable parts in this unit or in its accessories (other than the mobile phone). Any attempt to disassemble and/or repair this unit will result in voiding of the warranty.
5. Do not immerse any part of the unit in cleaning solutions. Instead, wipe clean with medical grade cleaners.
6. Do not touch the optical or illumination lenses except as described in the maintenance section of this manual.
7. Do not spray cleaning solution directly onto any part of this device.
8. The LED light is extremely bright. Do not stare directly into the light while turned on.
9. Do not leave the device on for more than 10 minutes at a time. Allow 15 minutes in the "off" position between uses.
10. Do not allow the device to come in contact with the patient.
11. No modification of this equipment is allowed.
12. MobileODT assumes no responsibility for any injury to anyone, or for any illegal or improper use of the EVA System, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or statement of intended use published in this manual.

Symbols and Markings



General Warning Sign

"On" (Located on the on/off switch on the device)

"Off" (power)



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<i>Symbol</i>	<i>Description</i>
	Serial Number
	Catalog Number
	Refer to instruction manual/booklet
	Prescription use only
	Manufacturing date
	CE Compliance Symbol
	Waste of Electrical and Electronic Equipment (WEEE) compliance symbol
	Manufacturer
	Date of Manufacture
	Authorized Representative in the European Union
	DC (Battery)
	Keep away from sunlight
IPXY	IP (International Protection) code

In the United States, federal law restricts prescription medical devices to be sold by or on the order of a physician, or properly licensed practitioner.