

EVA Pro

Instructions For Use



Thank you for purchasing an EVA Pro device, by MobileODT Ltd. Please read this guide carefully before using your device. The user guide can be found online at www.mobileodt.com.

Eva Pro has been designed to maximize safety and minimize strain for users and patients. However, precautions must be taken to further reduce the risk of personal injury or damage to the device.

Refer to the Declaration of Conformity for a list of the compliance standards and guidelines for the Eva Pro. MobileODT operates a Quality Management System that has been certified for compliance with the requirements of ISO 13485:2016.

The CE mark on this Product indicates it has been tested to and conforms to the Provisions noted in the Medical Device Regulation 2017/745 (MDR).

For further support, please contact us:



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



MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany
<http://www.mednet-eurep.com>



Training materials for the EVA Pro can be found at:
<https://kb.mobileodt.com/>

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INDICATIONS FOR USE

Intended to provide magnified visualization of the tissues of the vagina, cervix and external genitalia to aid in selecting areas for biopsy and diagnosing abnormalities as needed for a colposcopy exam. The EVA Pro is intended for use in hospitals, clinics and doctor's offices.

USE ENVIRONMENT

The EVA Pro is intended for use in hospitals, clinics and doctor's offices.

USER QUALIFICATION

The handheld EVA Pro Digital Colposcope (viewing the cervix) must be used by a physician or by medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures. MobileODT does not discuss or provide explanations of clinical procedures.

CAUTION: Read all warnings and cautions provided in these instructions before using the EVA Pro device.

DESCRIPTION

The EVA Pro Digital Colposcope provides assistance for clinician examination of the cervix. It is specifically designed for use in resource-limited settings. The device is a handheld, portable, battery-operated, with an LCD display and optical camera to assist diagnosis and treatment, in a safe, effective, easy to use package with sufficient battery life to sustain work for 4 hours. The EVA Pro device is not intended for insertion into the vaginal canal during colposcopy examination. The camera remains outside the vaginal cavity and functions comparably to a standard non-invasive colposcope in terms of providing magnified visual assistance to the clinician. There is no patient contact during the colposcopic examination.

Contact between the clinician and the device is mitigated through good clinical practice of wearing protective gloves, limiting contact to intact skin protected by operating gloves. It is well established that not only are colposcopes inherently safe for the intended use of cervical inspection, but that they are effective both



Figure 1: The EVA Pro Digital Colposcope

for improving visual acuity through magnification to aid the process of cervical intraepithelial neoplasia diagnosis, reducing false negative diagnoses, and have been demonstrated in combination with telemedicine and image capture to allow for remote diagnoses that are comparable to standard colposcopic examination, thus expanding the ability for appropriately trained nurses to perform colposcopy exams.

HOW SUPPLIED

The following components are included with the MobileODT EVA Pro:

- EVA Pro Digital Colposcope Device
- Two Removable Lithium-Ion Battery Packs
- Charging Base with A/C Adapter and Universal Plugs
- Hard Shell Carrying Case
- Stand Connector
- Instructions for Use
- **Optional Accessories:**
 - Tripod (portable) / Wheeled Stand

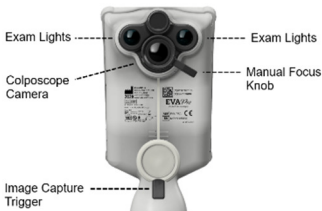


Figure 2: The EVA Pro device design

CONTRAINDICATIONS

There are no contraindications associated with this device.

RESIDUAL RISKS

The EVA System should not touch the patient. There are minimal risks to the patient. The system has been tested according to specific medical standards.

WARNING AND PRECAUTIONS

1. **No modification of this equipment is allowed.**
2. **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. The EVA Pro may not be used unless you or your organization meet the requirements and/or obligations under such laws and you assume full responsibility for any illegal purchase and/or use of the device. The EVA Pro 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.**

3. Although the EVA Pro complies with EN IEC 60601-1-2:2015 (4th ed.) EN 55011 (2009) +A1 (2010) CISPR 11 EN 55011:2016 for electromagnetic phenomena (EMC) for the Professional healthcare environment, the device may emit electromagnetic radiation that may affect the performance of other electrically powered equipment, or the performance of the device may be affected by electromagnetic radiation from other electrically powered equipment in the vicinity.
4. Other equipment could interfere with the EVA Pro, even if other equipment complies with CISPR emissions requirements.
5. **NOTE:** This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.
6. The LED light is extremely bright and should be the only illumination used as a light source during an examination. Do not stare directly into the light when it is in operation.
7. **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EVA Pro, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
8. Only connect the EVA Pro to secured, trusted Wi-Fi networks.
9. The EVA Pro batteries should only be connected to the Provided recharging base.
10. The EVA Pro device and accessories have not been tested for magnetic resonance imaging (MRI) safety. Avoid using MRI equipment.
11. Prior to touching the camera lens or the LED lights, please consult the manual.
12. The EVA Pro should only be transported in its protective carrying case to avoid overbalancing.
13. Do not immerse any part of the colposcope in cleaning solutions or any fluid.

14. Do not use strong detergents or alcohol under any circumstances for optics cleaning. This would lead to irrevocable damage to the optically-coated lens surfaces.
15. To limit contamination, use recommended disinfectant agents between each exam.
16. Do not use corrosive materials or strong cleaning materials other than those specifically prescribed on the casings or on the optics. Such materials lead to permanent damage of the painted surface of your colposcope and/or scratch the lens coatings of the optics. This leads to considerable loss of quality of the entire visual system.
17. If the LED light ceases to work, due to battery drain or LED burn out, stop using the colposcope and recharge the batteries. Sometimes a discharged battery will manifest via a flickering LED. In this case, recharge the battery to full capacity before continuing use.
18. **FCC CAUTION:** Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
 - a. This device may not cause harmful interference; and
 - b. This device must accept any interference received, including interference that may cause undesired operation.
19. This product complies with the US portable RF exposure limit set forth for an uncontrolled environment and is safe for intended operation as described in this manual. Further RF exposure reduction can be achieved if the product is kept as far as possible from the user body or is set to a lower output power if such function is available. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter. This device is intended only for OEM integrators under the following condition:
 - a. The transmitter module may not be co-located with any other transmitter or antenna;
 - b. If the condition above is met, further transmitter testing is not required. However, the OEM integrator is still responsible for testing their end-Product for any additional compliance requirements required with this installed module.
20. Per AAMI TIR69:2017, the risk associated with this device is assessed as Category D NEGLIGIBLE for wireless QoS needed for safe and effective operation.

21. WPA2 wireless AP recommended.
22. WiFi Connection Issues: If there are issues connecting to a WiFi network, ensure that you have the correct password and that you are entering it correctly. WiFi passwords are case sensitive. If problems still persist, restart the device, forget the WiFi connection, and try again. Ensure that other WiFi devices can connect to the WiFi successfully. Try connecting the device to another WiFi network. If problems still persist, user should contact customer service.
23. Patient Data Transmission Issues: If patient data transmission fails, please reboot the device and try again. Ensure that your WiFi connection to the Internet is functioning correctly. Ensure that no firewall or proxy settings on the WiFi network are limiting access to the internet.
24. The MobileODT EVA Pro device contains a 12V lithium-ion battery pack. Please observe the following practices:
 - a. Do not place the device on or near fires, heaters, other high temperature locations, or apply heat directly to the unit or battery pack.
 - b. Do not pierce the unit or battery pack with any sharp objects, strike the unit or battery pack with a hammer, tools, or heavy objects, step on the unit or battery pack, or otherwise damage the unit or battery pack.
 - c. Do not subject the unit to strong impacts or shocks.
 - d. Do not expose the unit or battery to water or any other types of liquid, or allow the battery to get wet.
 - e. Do not leave the unit or battery in direct sunlight and avoid storing in vehicles in extreme hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may result in a loss of performance and short battery life.
 - f. Remove the battery if the device is not likely to be used for some time.

SERVICE AND MAINTENANCE

There are no serviceable parts. If any failure has developed, contact MobileODT to purchase a replacement part or system. The EVA Pro includes a USB-C interface that is for maintenance use only.

The EVA Pro handle, charging base, and power supply are reusable and should be routinely cleaned with a clean damp cloth or with an anti-microbial wipe. Any service to the EVA Pro must be performed by MobileODT.

WARNING: Do not submerge the EVA Pro handle, battery charger, or battery in fluid of any type. It may short the electronics and cause an electrical shock to the user.

REQUIRED EQUIPMENT

Before using the EVA Pro, the following equipment should be accessible:

- Pre-charged battery. Full charge is recommended but not required.

HANDLING AND PREPARATION

Inspection Before Each Use

Before each use, perform the following:

General Inspection

- Inspect for visible damage to the EVA Pro handle, battery, and all connections.
- Make sure that no parts are missing or loose.
- Make sure that connecting elements between instruments function properly.
- Verify that the EVA Pro and accessories are in good working order by following the “Activating the Unit” steps outlined in the following section.
- If the battery is not already installed, insert a charged battery into the handle of the unit. The battery can only be inserted in a single orientation. Push the battery into place until the locking tabs snap; these tabs lock the battery into the handle.



Figure 3: EVA Pro Battery

WARNING: Examine all accessories and connections to the EVA Pro before use. Ensure that the accessories function as intended. Improper connection may result in accessory malfunction.

NOTE: The battery is removed by compressing the two locking tabs on the sides near the battery base releasing the lock and, while firmly holding the unit head, pulling the battery down and out of the handle.

Connection to stand

Together with your EVA System, MobileODT provides a device stand for stabilizing the colposcope while capturing an image. There are two types of stands: a wheeled stand and a portable stand. Below are basic instructions on connecting the colposcope to both models. See the detailed assembly instructions that came with the stand itself for further explanations.

1. Wheeled Stand

The wheeled stand includes two distinct parts: the base and the pole. During the exam, the wheel stand should be locked manually to improve the stability of the stand.

2. Portable Stand

The portable stand also enables a hands-free examination. This stand can be carried from location to location, can be folded for portability between exam rooms, or put into the accompanied carrying case to move between clinical sites.



Figure 4: EVA Pro connect to a wheeled stand

CAPTURING A CLINICALLY USEFUL IMAGE

Clinically useful images are critical for remote consultation, patient documentation, and quality assurance purposes. There are several factors to consider to ensure high quality images.

Stability

The colposcope should be in a stable position while capturing an image. The unit can be stabilized by:

1. Using a stand: The colposcope can be attached to a provided stand. The height of the stand should be the same as the height of the examination table (standard medical table height is 80-110 cm/31.5-43.5 inch).
2. Hand-wave feature: Images can be captured without touching the screen, through the hand-wave feature. This enables the user to momentarily hold their hand in front of the proximity sensor above the visualization screen in order to capture an image.

Positioning

Distance: The device should be positioned at a distance of 17-40 cm / 7-15.7 inches from the patient's cervix. **For best image results, position the device as close as possible to the cervix (within 20cm).**

Important: the colposcope should never come into physical contact with the patient.

Angle: The entire face of the cervix should be captured in the image, without any obstruction by the speculum. The colposcope lens should be aimed directly at the patient's cervix.

Illumination

The cervix should be fully illuminated, while avoiding any glare.

The LED light is powered by a rechargeable battery contained within the optical unit. The battery has a charge capacity sufficient for approximately 4 hours of continual use.

The colposcope reduces glare with a polarizer, however glare from the speculum reflection is still possible. If this is the case, reposition the colposcope and/or the speculum until there is less glare.

Focus

Adjust the distance between the colposcope and the patient. Once you have achieved adequate focus, as you zoom in and out digitally you can use the manual focus knob to re-adjust your focus.

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

PATIENT PREPARATION

The patient should be prepared according to clinic protocol for the appropriate type of procedure.

COMPLICATIONS AND SIDE EFFECT

No known complications to the patient will occur during digital colposcopic examination. If acetic acid or iodine is applied during VIA or VILLA, standard complications with their use may occur.

About EVA COLPO

Add history of present illness

In the EVA COLPO clinical application, users can enter details of patient present and past illness once the basic patient identifying information has been entered

by tapping on 'Add history of present illness.' You can enter the following information (none of the fields are mandatory):

- HPV status
- Date of last Pap/HPV test
- Pap result
- Previous cervical biopsy taken
- Previous cervical biopsy details
- Previous cervical ablative or surgical procedure
- Previous cervical ablative or surgical procedure details
- Previous evaluations and results
- Previous cervical ablative or surgical procedure notes
- Lugol's changes
- Satisfactory colposcopy
- Colposcopic impression
- Notes (this field allows you to record free notes)

Optional features

For users in some markets, depending on regulatory approval the following extra features may be available:

- Quality Frame
- Zoom Telehealth

TELECONSULTATION (Zoom Telehealth)

About the Teleconsultation feature

The teleconsultation feature on the EVA System allows for remote proctorship and consultation among clinicians.

By using the third party Zoom application on the EVA device, a clinician in a remote location can supervise the clinician at the point of care in real-time.

Installing the Zoom Application

- To request the Zoom application activation, please send an email to MobileODT support team: support@mobileodt.com and provide your username and device serial number.
- To install Zoom on the device, follow customer support instructions.
- Once the Zoom application is installed, you will be able to share your EVA device screen:
 - Open the Zoom app and sign up or sign in.
 - Click on 'Start A Meeting'.
 - Turn the video off.
 - Enable 'Use Personal Meeting ID'.

- To share the screen, click 'Share' at the bottom and share the screen.
- Participants at the remote location should visit <http://zoom.us> and select 'Join A Meeting' (they do not have to sign up to Zoom).
- Tap your screen while in the Zoom application to get your personal meeting ID and give it to the remote consultant.
- The remote participant enters the meeting ID that you provided into their screen under join a meeting.
- Once they have joined the meeting, they should now be able to see your screen and speak directly to you via the EVA device.

DIRECTIONS FOR USE

Read all instructions before use.

Activation (ON/OFF) Button: Press once to turn unit on. The device will power on and the display will boot will show a boot logo. If the battery is low upon startup, the device will show low battery on the display, then shut down. After activation, the EVA Pro can be used for digital colposcopy.

SOFTWARE DIRECTIONS FOR USE

EVA PORTAL

Welcome screen

You will be presented with the Welcome screen. Here you can:

- Set up - for new users
- Log in - for existing users
- Reset your password - by pressing "Forgot password?"
- Contact MobileODT
- Review our terms and conditions, as well as our privacy policy.

Setting up a user

1. If you are new to the EVA System and did not set the password on an EVA device or on the portal click on “Set up.”
2. Enter the email associated with your EVA user account.
3. Click on ‘Send activation code.’

Set up EVA System account

Please enter your email associated with your EVA account.

Email

Email

Send activation code

Already have an account? Log in

Set up EVA System account

Please enter your email associated with your EVA account.

Email

XXXXXXXX@XXXX.XXX

Send activation code

Already have an account? Log in

4. An email will be sent with a code that needs to be entered on the next screen.
5. Enter the activation code you received
6. If you did not receive an email, check your spam and trash folders.

You can now activate your account through the EVA portal or on your EVA device. Please enter the activation code to complete the sign-up process.

x1234567

You will only need to activate your account once. After your initial sign-up is complete you will automatically be able to access the EVA portal or your EVA device using the same information.

Activate Account

An activation code was sent to this email: someuser@someemail.com if it exists in our system. Please enter the activation code you received.

Activation code

Activation code

Activate Account

Didn't receive an activation code or had a mistake in the email address?
Re-enter email address and resend code

7. After entering the activation code, you will be requested to select a password.
8. The password requires a minimum of eight characters including a capital letter, a lowercase letter, one number and one special character. This password will be used to access your EVA account, both on the portal and on EVA devices (application).

Create a password

To complete activation, please create a password for your account. Your password must have a minimum of eight characters including a capital letter, a lower case letter, one number and one special character

New password

Please re-enter your password

Done

Logging in

1. If you have already set up your EVA user and have chosen a password in the system press 'Log in'.
2. Enter the email and password for the EVA System (the same used in the EVA device to create your EVA account).

Log in

Email
Required

Password
Required

[Forgot your password?](#)

Log in

[New to the EVA System? Set up](#)

Forgot Password

1. Click "Forgot password?" on the welcome screen.

Log in

Email
Required

Password
Required

[Forgot your password?](#)

Log in

[New to the EVA System? Set up](#)

2. Enter the email address associated with your EVA account.

Reset password

Please enter your email associated with your EVA account.

Email
Required

Send temporary password

3. An email will be sent to the email entered with a temporary password.

We have received a request to reset your EVA System password.

Your temporary password is: **419814**

Please enter this temporary password the next time that you sign in to either the EVA portal or your EVA device. After you enter the temporary password, you will be requested to choose a new password.

If you did not request to reset your password, you can safely ignore this email and your password will remain as it was.

We're here to help you, and please feel free to reply to this email if you need any further assistance.

4. Enter the temporary password and create a new one, then enter it once again.

Viewing patient records on the Portal

Upon successful login, you can view a list of all the cases you have performed with the EVA System with exam notes.

1. To review a patient's exam notes, click on the name of the patient in the list.
2. Deleting a patient record: hover the cursor over a patient name, and a delete button is displayed in the right column. When the deletion is confirmed all the data related to the patient is permanently deleted from the system.

Searching for patient records

To search for a patient, enter the patient's first name, last name or medical record number by typing in the appropriate search field at the top of the screen and tapping enter. The relevant results will be presented on the screen.

Reviewing and editing patient examination records

In the patient examination record, all the information collected about the patient during current and past examinations is displayed: Patient details, documentation of the exam, images, annotations, and history of present illness.

1. If multiple examinations of the same patient have been collected, they will be shown on the top of the patient examination record. The user can choose to view the specific examination by clicking on the date of the examination.
2. An option to delete an exam is displayed next to exam details. Once it's confirmed all the exam's data is permanently deleted from the system.

Editing the Exam

1. In the patient examination record, the user can edit the documentation section and the history of present illness by pressing the edit icon.
2. When the user on the edit icon in the patient record, a modal with all the relevant information appears and the user can change the field. To save the changes, the user needs to press on "Save".



Viewing images and annotations

1. Viewing images: In the patient examination record, the user can open a large size version of any image by clicking on the thumbnail of that image.
2. Deleting images: In the patient examination record, the user can select several images to delete. After selecting the images click on the "Delete" icon at the top right and confirm to delete the images. Once it's confirmed all the selected images are permanently deleted from the system.
3. In the image gallery view, the user can delete the specific image by pressing the 'Delete' button in the left bottom corner. Once it's confirmed the image is permanently deleted from the system.
4. In order to switch between images, the user can either press on the thumbnails below the large image to jump directly to that particular image or use the arrows on both sides of the screen to navigate through the images.
5. Download image – The user can download an image by pressing the 'download' button.

6. Show/Hide Annotations - By clicking on the annotation button on the top left of the screen, users can view or hide any annotations that were made on that particular image.
7. Annotation description/notes are displayed on the right-hand side of the screen. Locations of annotations are shown on the image.
8. Add annotation – By pressing ‘Add Annotation’, the user can add annotation to every image in the exam. The following fields need to be filled: annotation position, biopsy taken, diagnosis and additional notes.
9. Edit/Delete annotation – When the user’s mouse is on a specific annotation, the delete and edit buttons are displayed. To edit the particular annotation, the user can press the ‘edit’ button. To delete an annotation, the user can press the ‘delete’ button.
10. View Green filter - While in large image view, a user can also apply the green filter to that image. The green filter can be applied or removed by pressing the green filter button at the top left side of the screen.
11. Whenever it is turned on, it can be found on the capture screen instead of the green filter button.
12. To close the large size image, the user should press the X button on the top right corner.

Adding notes

The user can enter free notes and view them in the examination record.

To enter a new note, the user needs to click on “Add note” button and a pop up is displayed where the user enters free text and press Save. The new note will appear in the notes section.

Help

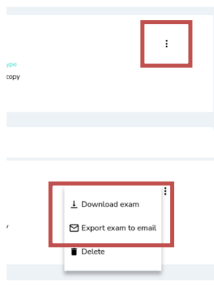
The support button at the left side of the screen allows you to send a support request to the MobileODT support team. Enter all the details requested on the support form that opens.

Export & Download

Export to PDF

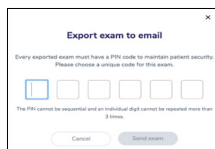
In the exam page the options to export or download a PDF is available.

1. A 6-digit PIN code is requested to ensure the PDF file of the examination will remain secure. The PIN cannot be sequential, and an individual digit cannot be repeated more than 3 times.
2. After setting the pin, the PDF will be sent to the user's email or downloaded to the computer.
3. In order to view the exam PDF file, the user will need to enter the code they had previously selected.



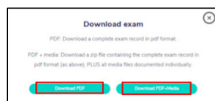
Option 1- Export exam to email:

Upon choosing this option, the user will receive a link to their email from which the exam can be downloaded.



Option 2- Download exam:

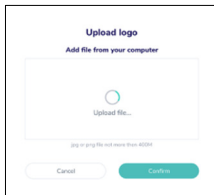
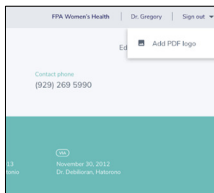
Upon choosing this option, the user will be able to choose to download only the exam's report as PDF, or the PDF along with the exam's media files.



Add logo to PDF

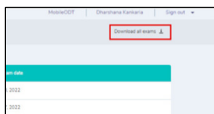
Clinical admins can add a personalized logo to exported pdf exam report.

1. When viewing the patient details, select 'Add PDF' from the settings menu.
2. Then, either drag and drop, or browse the local computer for your selected file and upload to the EVA Portal. Click 'add logo' to attach the selected logo to the PDF for export.
3. Image files must be no more than 4MB and in JPG or PNG format.
4. Click confirm to have this logo automatically added to any future PDF reports.



Download all exams (Bulk Download)

1. At the top right of the patient menu there is an option to bulk download all exams created by you. This will enable you to download all exam data that exists within your entire EVA System account.
2. The bulk download feature will send a request to MobileODT's servers to export all of your data in encrypted files. Processing the request may take between several minutes to hours.
3. Once the Processing is complete, an email will be sent to your account with a link that includes all the data you have as an encrypted ZIP file. The links are encrypted with a PIN code and will be available for 72 hours.
4. Each Zip file contains a CSV file, which lists all the exported data that exists within the Zip file, and a folder containing each exam as a separate file (PDF report and media files).
5. Along with links to the ZIP files, you will also receive a link to a CSV file with a summary of all downloaded exams. This summary is a content list indicating on which ZIP file each exam exists, and if it was downloaded

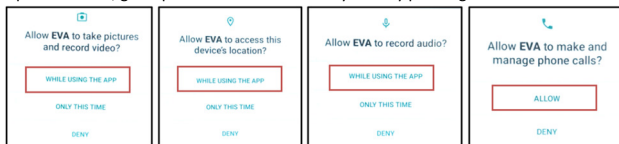


- successfully. If an exam were not downloaded, it is still available to download manually from the portal.
- Each download request requires a 6-digits PIN. You will be Promoted to create a PIN for that download. This PIN will be used to open all encrypted ZIP files.
 - Bulk download can be generated once every 24-hour period.

EVA System software application

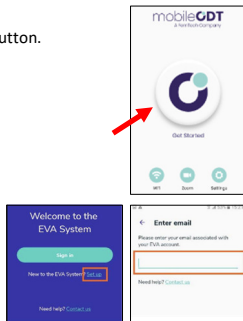
Grant the EVA app permissions

Upon first boot, grant permissions for the EVA system by pressing allow:

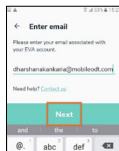


Setting Up a New User

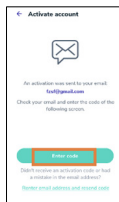
- Enter the EVA app by clicking the start button.
- On the Welcome screen, tap on 'set up'.
- Enter the email address that was used to create your EVA account.



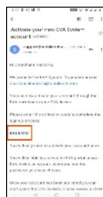
4. Tap on 'Next'.



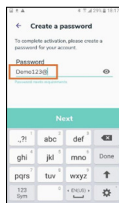
5. An email will be sent to that address with an activation code that needs to be entered in the next screen. Tap on 'Enter code'.



6. Enter the activation code you received in your email and tap on 'Next'. An example for such an email:



7. Set a password - the password requires a minimum of eight characters including a capital letter, a lowercase letter and one number. Tap on 'Next'. This password will allow you to access the EVA System including the EVA portal.



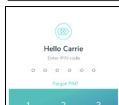
8. Create a 6-digit secure PIN. The PIN will give you secure access to this specific EVA device. Tap on 'Save PIN'.



9. Read and accept the terms of use before using the app. Click on 'I Accept'.

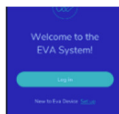


10. You will be directed to the login page. Enter your PIN to enter the application.



Log in (existing user)

1. Tap 'Log in'.
2. Enter email and password for the EVA System. Tap on 'Next'.
3. Log in with PIN/Password while online or offline.



Reset PIN

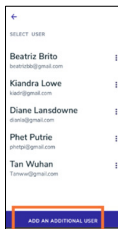
If the user that is presented is yours, enter the PIN to access the device. You will have 5 attempts to enter the PIN correctly. If you do not remember the PIN, tap on 'Forgot PIN?' and it will redirect you to the 'sign-in' screen'. On this screen, you will be able to log in using your email and password.

Changing the user

If the user that is presented on the screen is not your user, tap on 'CHANGE USER'.

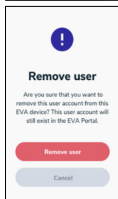


The app shows all the users that were added to that particular device. If your email is not in the list tap on 'ADD AN ADDITIONAL USER', and it will redirect you to the sign-in/set up screen.



If you wish to remove a user from the device, you can press the menu button (three dots) next to the specific user and then select "Remove user".

Once it's pressed a confirmation pop-up is displayed.

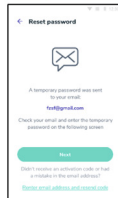
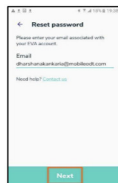


Please note: The user in question is only removed from this specific device. All the data that this user had created is available through the EVA Portal. The user will still be present on any other EVA device that they may have logged into. This user can also add his/her account to this device again in the future.

Reset EVA account password

A User's EVA account password can be reset through initial log in menu:

- Tap on 'Log-In' and then 'Reset password'.
- Enter your email address associated with your EVA account and tap on 'Next'.
- A temporary password will be sent to the email (in this example, fzsfg@gmail.com). Tap on 'Next'.
- Enter the temporary password in the dedicated field. Enter a new password in the dedicated field. The password requires a minimum of eight characters including a capital letter, a lowercase letter, and one number and one special character. Re-enter the password and tap on 'Next'.



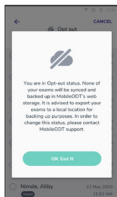
Opt-out status

A user or organization may choose to operate in 'Opt-out' status, meaning that none of their exam data will be uploaded or synced to the EVA Portal online storage.

Opt-out status is managed by MobileODT administration. Users can request that opt-out status be applied or removed from their account by contacting support@mobileodt.com.

While in opt-out mode the app is not synced with the EVA Portal and cannot link past exams conducted on a patient with the same MRN.

It is advised that exam data be regularly manually exported using USB and backed up on a local computer (see 'Exporting the Exam' section for instructions).



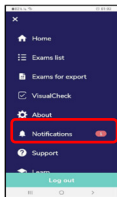
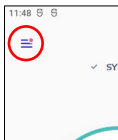
Notification Center

Users will be notified through the notification center of important information intended to maintain the smooth running of their EVA System, such as when a software update is available.

Users are alerted that they have unread notifications when they open the EVA device, by a red dot appearing on the Main menu icon on the top left.

When a user enters the Main menu, a red indicator will appear next to the Notification section.

To read notifications, tap on the Notification listing in the main menu.



Performing an exam

Press 'Start colposcopy'.

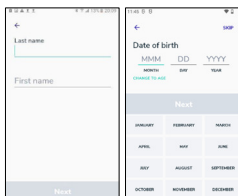


Enter identifying patient information

For each patient, you can enter the following fields: Medical Record Number (MRN), first name, last name, date of birth (or age if date of birth is unknown,) and a contact phone number.

If a medical record number is entered, the subsequent fields can be skipped.

If no medical record number was entered, first name, last name, and date of birth (or age) will be mandatory.



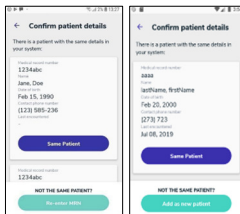
MRN can be entered manually or by scanning the barcode by pressing 'Scan patient label'.

Please note that at this stage you need to hold the barcode in-front of the lens.

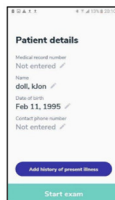


If the MRN or the same combination of first and last names with the same date of birth already exists in the user's account, the system will ask the user if the new patient that was entered is the same patient that already exists.

The user can either click 'Same patient' to add the new exam to the existing patient record, or click 'Re-enter MRN' or 'Add as new patient' if it is not the existing patient. Please contact Customer Support if there appears to be an issue with the details of an existing patient.



A summary of all entered information will be displayed with an option to edit every field.

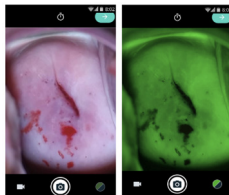


Capture images and videos

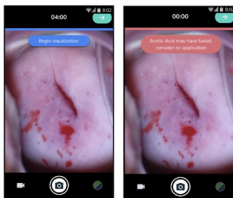
Tap on 'Start exam' and the visualization screen will be displayed.

Follow these steps to ensure you are capturing clinically-useful and focused images:

- Adjust the device at the appropriate working distance from the patient (typically between 17-42 cm).
- Adjust the fine focus knob to achieve optimal focus.
- Pinch in or out with your fingers on the screen to zoom in and out.
- To use the green filter, tap on the green button on the bottom right.



Once acetic acid is applied, it is recommended to use the timer. After applying acetic acid to the cervix, tap on the stopwatch icon at the top of the screen. A countdown of one minute will start. After one minute another countdown of four minutes will start. It is advisable to take and capture images and biopsies within this 4-minute window of time.



Capture images by tapping the capture button on the bottom middle of the screen or by clicking the image capture trigger on the device handle.

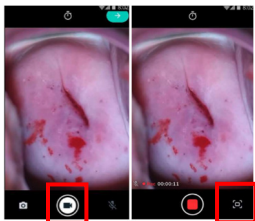
You can also capture images without touching the device screen. To do that: move the hand in a hi-five motion towards the top of the screen. You don't need to touch the device when doing so.

When you finish capturing images to your satisfaction, tap on the green arrow button at the top right of the screen and you will be redirected to the image gallery.

To capture video footage, tap the video camera button on the left side of the screen.

You can also capture images while recording by pressing the right-hand side at the bottom of the screen.

If you have a demo or a distributor account, you can take only 3 images and 1 video.



Changing settings during an exam (Camera menu)

The camera's settings can be managed directly during an exam by accessing the camera menu. The camera menu can be opened by clicking the settings button found on the top of the image capture screen.

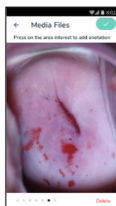
To switch a feature on or off click on the toggle button to the right of each feature. Depending on your clinical scenario, a number of settings may be available,

- Green Filter
- Hands-free image capture

Review media files

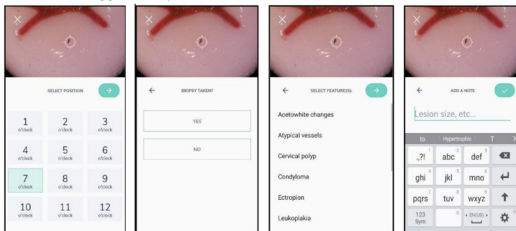
The files that were captured are displayed in the order in which they were taken - from first to last.

- Swipe with your finger to the left to see the next file and swipe to the right to see the previous file.

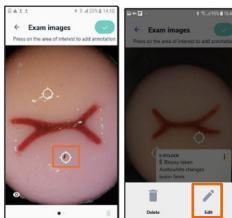


Add annotations

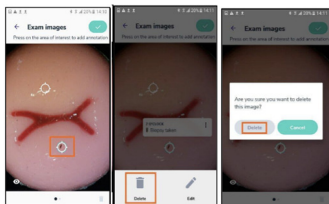
To annotate an image, tap the location on the image you would like to annotate, and follow the suggested options to record the relevant details.



To edit an annotation, tap on the annotation and tap on edit, following the suggested options to edit the relevant details.



To delete an annotation, tap on the annotation and tap on delete. A warning confirming that you want to delete that annotation is shown.



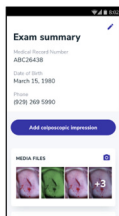
After all the data is entered tap on the green button at the top right of the screen.

Summary

All the information entered is displayed on the summary page.

You can edit patient's details by pressing the edit button at the top of the screen.

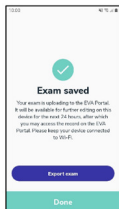
To finalize the documentation, tap on 'Finish exam' when done. The exam will start uploading to the EVA Portal. The exam will be available for further editing on the device for the next 24 hours.



Exporting the exam

After tapping on 'Finish exam', an option to export the exam is available. The user can choose between exporting to an email or to a folder on the device from which the exams can be exported and backed up manually on a local drive.

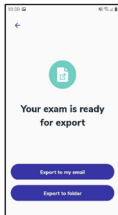
Tap on the button 'Export exam'.



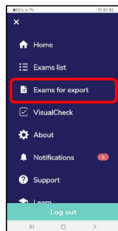
A 6-digit PIN code is requested to ensure the files of the examination will remain secure. The PIN cannot be sequential, and an individual digit cannot be repeated more than 3 times.



After setting the pin, the user will need to choose whether to export to the user's email or to export to a folder.

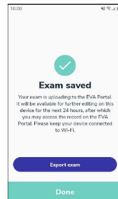


- Upon choosing 'Export to my **email**', the system will start exporting the examination report as a PDF. When the upload Process to the portal is completed, the exam will be sent to the user's email.
- Upon choosing 'Export to **folder**', the system will start exporting the examination report and media as a ZIP. When the zip is created, the exam will appear on the 'Exams for export' page.



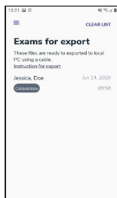
If you don't want to export the exam, tap on 'Done' and the home screen will be displayed.

Exams can also be selected for export via the Exam list screen on the main menu. See the next section for details. Only exams that have been completed can be exported.

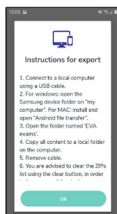


Back up exams on a local drive:

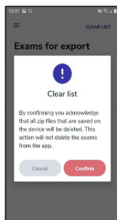
The 'Exams for export' page can be reached from the main menu and presents a list of all exams that exist on the device as ZIP files that are ready to be exported manually and backed up.



The 'Instructions for export' explain what should be done in order to export the exams from the device using a USB cable.



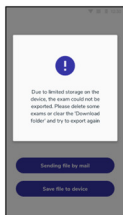
In order to clear this list, which will clear up space in the external folder of the device, the user should click the 'Clear list' button.



Limited storage preventing export

If the internal EVA device storage is at maximum capacity, then it will not be possible to export any more files to ZIP format until the storage is cleared and more space is available. In this case, a warning popup will be displayed advising the user to return to either the Exams for export or Exam lists and delete exams.

It is advisable to remove exams in ZIP format from the device after they have been manually exported via USB to a local computer to ensure that there is free space on the EVA device.



Reviewing exams on the app

To view examinations from the past 24 hours or to see the process of uploading examinations to the EVA Portal, tap on the menu button the top left in the home screen and tap on 'Exams'.

The Exams list shows exams created in chronological order with the most recent at the top. An icon next to each exam indicates the sync status (upload to the EVA online portal)

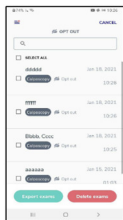
One of four options might be shown; draft (if the exam has not yet been completed,) In progress (if the exam is in the process of being synced,) uploaded (if sync is completed), or Opt-out (if exam was taken while being opt-out).

A USB symbol next to exam (in any state) indicates that an exam has been exported to the ZIP folder and ready to be exported manually via USB connection.

To view any exam on the device, click on any of them and the system will redirect to edit the exam.

Search bar is available on top of the exam list. Exams can be searched by patient's Name, Last name or MRN.

No sync icon will be shown next to exams taken while in Opt-out mode. An icon at the top of the screen will indicate that the device is currently in opt-out mode. An



icon will still indicate those exams that are ready for manual export via USB.

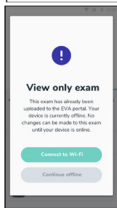
Exams can be selected for export to ZIP (for manual export via USB) or deletion by clicking on the 'Select' button at the top right of the screen. Individual exams can then be selected for export or deletion from the device.

- Any exams that have previously been synced to the EVA Portal will still be saved on the Portal even if they are deleted from that specific device. Any exams captured in Opt-out mode or that have not been synced, will be permanently deleted from the system and cannot be retrieved. It is advisable to ensure that exams have been backed up either by manually or by syncing to the EVA Portal before deleting from the EVA Device.
- Only exams that have been completed can be selected for export to ZIP. Exported exams can be reached via the main menu under "Exams for export."

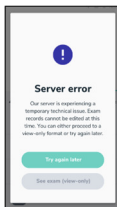
In the 'Uploaded' tab the examinations that finished uploading are displayed for 24 hours. Afterward, the exams can be viewed on the EVA portal: <https://eva.mobileodt.com>.

If the device is not connected to Wi-Fi, an option to connect to Wi-Fi is presented. The upload process only works if the device is connected to the internet.

If the device is not connected to Wi-Fi the exams in the device will be available in 'view mode' only.



If there is a server error the exams will also be available in 'view-mode' only.



Deleting an exam

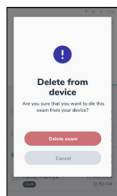
Users are able to delete exams and remove them permanently from that specific EVA Device.

Exams can only be deleted if they have been, one of the following:

- Synced to the online EVA Portal (where they are stored permanently unless deleted from the Portal);
- Exported as a ZIP file to the device Export internal storage for manual export via USB;
- Were a draft exam that was never completed.

If any exams selected do not fit these criteria for deletion, then a popup message will alert users to remove those exams from the deletion list.

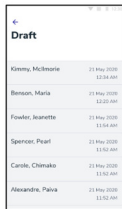
A confirmation popup is displayed once an exam is selected for deletion. **Exams cannot be retrieved once deleted.**



Exam Drafts

An option to save 'exam drafts' is available after entering the patient details. The exams are saved as draft and are not synced until the exam is finished.

To access all the drafts, see the Exams list via the Main menu.



Draft	
Kinney, McMorrie	23 May 2020 12:54 AM
Benson, Maria	23 May 2020 12:20 AM
Fowler, Jeanette	23 May 2020 11:54 AM
Spencer, Pearl	23 May 2020 11:52 AM
Carole, Chimako	23 May 2020 11:52 AM
Alexandre, Palva	23 May 2020 11:52 AM

About

1. To access the "About" section tap on the menu icon the top left icon the home screen.
2. Tap on "About".
3. In the "About" section users can review the version of the app, the release date and device ID and read MobileODT's Terms of Use and Privacy Policy.

Handwave feature

The handwave feature allows users to capture images without touching the device. The handwave feature should be turned on, when performing an exam to capture an image. To use this feature, move the hand in a hi-five motion towards the top of the screen. This feature is configurable from the camera setting menu.

Support

1. To reach out to MobileODT Support, tap on the menu icon at the top left of the screen.
2. In the menu section tap on 'Support'.
3. The support screen allows the user to connect with the MobileODT Support team for further assistance.

Learn

1. To access further training resources, tap on the menu icon the top left of the screen.
2. In the menu section tap on 'Learn'. This button opens up MobileODT's knowledge center, where you can find additional articles and videos.

Log out

1. To log out tap on the menu icon the top left of the home screen.

2. Tap on the 'Log out' button.

SHUTTING DOWN

At any point, the EVA Pro can be reset or shut down by pressing and holding the activation button for approximately three (3) seconds. The power menu will display. Tap 'Power Off' to shut the EVA Pro down. Tap 'Restart' to restart the EVA Pro.

RECHARGING THE BATTERIES

- Batteries should only be recharged when the battery and charger are dry.
- Plug the battery into the charging adapter.
- Plug the charging adapter into an A/C outlet.

NOTE: The charger can be plugged into an A/C power outlet of 100-240VAC, 50/60Hz, with the proper country adapter.



Figure 5: Battery Charging

- The red 'charging' LED on the charger should illuminate.
- A completely discharged battery should fully recharge in about two (2-4) hours. The LED on the charger will turn green when the battery is fully charged.
- The EVA Pro batteries are lithium-ion batteries and cannot be charged while connected to the EVA Pro handle. The EVA Pro handle cannot be connected to supply mains.
- There is an internal lithium-ion coin-cell battery (CR1220) that can only be changed by MobileODT.

EXTERNAL SCREEN MIRRORING

Using a micro HDMI cable and an external screen monitor, you can extend your EVA Pro display onto a larger screen and enjoy an enhanced screen visualization.

Required Equipment:

- EVA Pro device
- External screen monitor with an available HDMI port (or HDMI – VGA adaptor)
- Micro HDMI to HDMI cable (not supplied by MobileODT)

Step 1: Connect the Micro HDMI Cable

Insert the micro-HDMI plug into the micro-HDMI port on your EVA Pro device.

Note: the port is in the base of the device.



Step 2: Connect the other end of the cable (the standard HDMI plug) to an available HDMI port on the external screen monitor.

Step 3: Switch On the External Screen Monitor

Turn on the external screen monitor using its power button or remote control.

Step 4: Switch On Your EVA Pro device

Turn on your EVA Pro device and start using the EVA app.

Step 5: Adjust the Display Settings (if needed)

Depending on your monitor, you may need to adjust display settings. Make any necessary adjustments to match your preferences.

Step 6: Enjoy Your Extended Display

Your device should now be mirrored onto the external screen monitor. You can now use the monitor to view the content from your EVA Pro.

Step 7: Disconnecting the micro-HDMI Cable

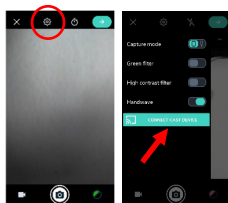
When you're finished using the external screen monitor, switch off the EVA Pro device and the monitor and carefully disconnect the micro-HDMI cable.

CASTING

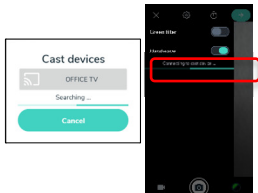
Wireless screen mirroring, referred to as “casting”, is supported for the camera preview and the media gallery. At this time, Chromecast is the only supported casting device.

Casting the Camera Preview

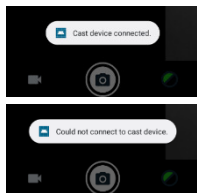
1. Open the settings panel and tap the button labeled "CONNECT CAST DEVICE".



2. A window will be displayed, showing the available cast devices. Select the device you want to cast to. A progress indicator will appear while the device connects.

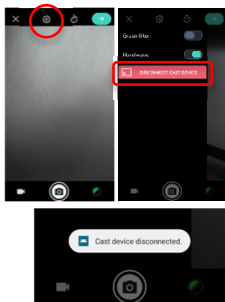


3. After a successful connection to the cast device has been established, the following notification will appear, "Cast device connected." and the casting will start.
If a connection to the cast device cannot be established, the following notification will appear, "Could not connect to cast device."



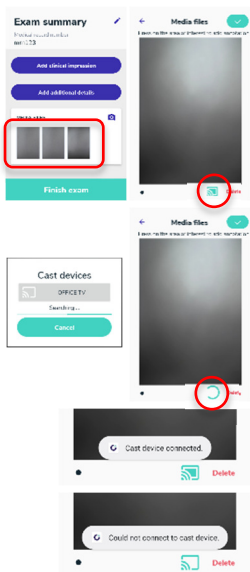
4. While casting is enabled, the current camera preview will be shown on the cast device. Exiting the camera preview screen will disconnect the cast device, but switching between the camera preview screen and the gallery will not disconnect the cast device.

- To stop the casting of the camera preview, open the settings panel and tap the button labeled "DISCONNECT CAST DEVICE". Casting will stop and a message will appear that says, "Cast device disconnected." The same message will appear if connection to the cast device is lost.

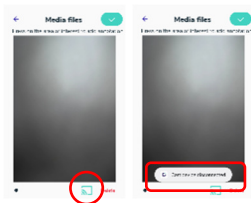


Casting of the media gallery

- From the "Exam Summary" screen, tap on one of the images in the "Media Files" section. Tap on the cast icon in the bottom right corner of the screen.
- A notification will appear that will present the available cast devices. Select the device you want to cast to. A progress indicator will appear while the device connects.
- After the connection to the cast device has been established, the following notification will appear, "Cast device connected." and the casting will start. If a connection to the cast device cannot be established, the following notification will be presented, "Could not connect to cast device."



4. While casting is enabled in the gallery, the current image or video will be shown on the cast device. Exiting the gallery will disconnect the cast device, but switching between the camera preview screen and the gallery will not disconnect the cast device.
5. To stop casting of the gallery, tap the cast button in the bottom right corner of the screen. Casting will stop and the following notification will be presented, "Cast device disconnected." The same notification will appear if connection to the cast device is lost.



CLEANING AND INSPECTION

The EVA Pro handle is reusable and requires specialized cleaning after each use. Follow the proper cleaning instructions for cleaning the device using the following procedure:

Handle and Battery Cleaning Procedure:

- Disassemble the EVA Pro into two separate parts (device, battery)
- Thoroughly wipe all surfaces of the EVA Pro device and battery with a mild cleaning solution (i.e., 70% isopropyl alcohol) or disinfectant and damp cloth. The cleaning solution or disinfectant should not be applied directly to the EVA Pro display. Pour/spray the cleaning solution or disinfectant onto a cloth and ensure that the cloth is evenly damp prior to cleaning the EVA Pro device and battery.
- Do not allow fluids to enter the EVA Pro. Do not sterilize the EVA Pro device or battery.
- Special caution should be used not to scratch the camera lens or display.

INSPECTION

MobileODT recommends that the EVA Pro handle be regularly inspected every month for visible damage. The following concerns should be addressed immediately:

- Signs of deterioration or obvious damage to the unit
- Signs of damage to any connector
- Accumulation of lint or debris on or around the unit

In each case, discontinue using the unit. If the unit is damaged externally or has a damaged connector, contact MobileODT. If the unit has accumulated dust or debris, follow the cleaning Procedure to remove the debris.

TROUBLESHOOTING

The EVA Pro has no user-adjustable controls or diagnostic tests. If the unit fails to respond as expected, try the following steps before contacting MobileODT's Support team:

1. If the EVA Pro will not turn on, please verify that the battery is fully charged. To prevent a low battery during a procedure, charge the battery before each day of procedures.
2. If the EVA Pro app is not responding, restart the EVA Pro by turning it off and on.

DEVICE DISPOSAL

When the EVA Pro device or battery are no longer functional or show signs of wear and damage, they should be disposed of in the same manner as electrical waste. To order additional devices/accessories or replacement accessories, contact info@mobileodt.com.

WARRANTY AND RETURN POLICY

If you or your organization purchased the device directly from MobileODT then MobileODT warrants that the Device will be free from defects in material and workmanship when used normally in accordance with the then-current Terms and related documentation for a period of one (1) year from the date of pickup/delivery of the EVA Pro device.

This Warranty does not apply: (a) to damage caused by operating the Device outside MobileODT's instructions; (b) to damage caused by accident, abuse, misuse, fire, liquid contact, earthquake or other external cause; (c) to damage caused by use of the Device with a third party component or product; (d) to damage caused by service performed by anyone who is not a representative of the MobileODT; (e) to a Device that has been modified to alter functionality or capability without the written permission of MobileODT; (f) to defects caused by normal wear and tear or otherwise due to the normal aging of the Device; (g) if any serial number has been removed or defaced from the Device; (h) any stolen Device or if MobileODT receives information from relevant public authorities that

the Device has been stolen; (j) if you are unable to deactivate passcode-enabled or other security measures designed to prevent unauthorized access to the Device, and you cannot prove in any way that you are the authorized user of the Device (e.g. by presenting proof of purchase); or (k) to any damages caused due to data loss if you do not back up such data onto MobileODT's cloud platform ,through EVA System Portal, for any reason.

MOBILEODT SHALL HAVE ABSOLUTE DISCRETION TO DETERMINE WHETHER TO REPAIR OR FIX A DEFECTIVE DEVICE.

TECHNICAL ASSISTANCE

For technical assistance, email MobileODT Support team at:
support@mobileodt.com

TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice. A specification referred to as "typical" is within $\pm 20\%$ of a stated value at room temperature (25°C/77°F) and utilizing a sufficiently charged battery pack.

DEVICE PARAMETERS

Power Parameters

Power Supply:	12 VDC
	Rechargeable Lithium-Ion
Battery Pack:	3-cell 3.2AH Battery Pack
	BMS overcharge Protection
Battery Charger:	12.6VDC, 1.8amp output
	Charge Time: 2-3 hours
Full-Charge Activation:	Until low-battery indicator illuminates
Power Output:	49 Watts
LED Light	White Cool 5700K

Digital Colposcope

Working Distance:	17-40cm
Focus Mechanism:	Manual
Optical Magnification	3x
Digital Magnification:	9x
Field of View:	15.6°
Direction of View:	0°
Aperture (F#):	>5
Average On-Axis Vertical Resolution:	15.75 line-pairs/mm
Average On-Axis Horizontal Resolution:	15.75 line-pairs/mm
Average Off-Axis Vertical Resolution:	11.56 line-pairs/mm
Average Off-Axis Horizontal Resolution:	10.33 line-pairs/mm
Image Resolution Pixels:	2016 X 2880 (5.8 megapixels)

Display

Display area:	62.10(H) X 110.40(V) 5.0in Diagonal
Number of Pixels:	720 X 1280 (0.92 megapixels)
Display Colors:	16.7M colors

Storage Capacity

Total System Storage	16 GB
Available User Storage	8 GB

Dimensions and Weight

Width:	3.2 inches (8cm)
Height:	9.5 inches (24cm)
Depth:	4.5 inches (11.5 cm)

Weight:	15.4 oz (435g)
Operating Conditions	
Ambient Temperature:	10°C to 40°
Relative Humidity:	0% to 80% non-condensing
Altitude:	2000m
Transport and Storage	
Ambient Temperature:	10° to 40°C
Relative Humidity:	0% to 80% non-condensing
General Info	
Type B Applied Parts	
IP21 Rating	Solid particle protection: Level 2 (>12.5mm)
	Liquid ingress protection: Level 1 (dripping water)
Wireless Communications	
Wi-Fi IEEE 802.11	ac/a/b/g/n; transmits at 2.40 to 2.48 GHz at +16dBm Operating Range: 50m
IEEE 802.15.4 Bluetooth class II	Bluetooth 2.1_EDR/BLE 4.2; transmits at 2.40 to 2.48 GHz at +16dBm Operating Range: 20m

Electromagnetic Compatibility Guidance		
Manufacturer's Declaration – Electromagnetic Emissions		
The EVA Pro is intended for use in the electromagnetic environment specified below. The customer or the user of the EVA Pro should ensure that it is used in such an environment.		
Emissions Test	Compliance	EMC Environment Compliance
RF Emission	Group 1	The EVA Pro uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
CISPR 11		
RF Emission	Class A	The EVA Pro is suitable for use in professional healthcare environments.
CISPR 11		
Conducted RF Emissions	Not Applicable	
Radiated RF Emissions	Complies	
Harmonic Distortion	Not Applicable	
IEC 6100-3-2		
Voltage Fluctuation and Flicker	Not Applicable	
IEC 61000-3-3		

Manufacturer's Declaration – Electromagnetic Immunity			
The EVA Pro is intended for use in the electromagnetic environment specified below. The customer or user of the EVA Pro should ensure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
IEC 6100-4-2 – Electrostatic discharge (ESD)	±8 kV contact	Complies	Not Applicable
	±15 kV air	Complies	
IEC 61000-4-4 – Electrical fast transient/burst	2kV Mains 100kHz	Not Applicable	No external connections
	1kV Signal/Data 100kHz		
	2kV Control 100kHz		
	100kHz rep Rate		
IEC 61000-4-5 – Surge	Mains 1kV LL, 2kV LG	Not Applicable	No external connections
	DC 0.50.5kV LG		
IEC 61000-4-6 – Conducted Disturbances induced by RF fields	0.15-80MHz 3Vrms	Not Applicable	No external connections
	Frequencies of main interest at 6Vrms		
	Amplitude Modulation 1kHz sine 80%		
IEC 6100-4-11 – Voltage dips, short interruptions and voltage variations on power supply input lines	100% for 0.5 cycle at 0/40/90/135/180/225/270 & 315	Not Applicable	No external connections
	100% for 1 cycle		
	30% for 25/30 cycles		
	100% for 250/300		
IEC 61000-4-8 – Rated Power-Frequency Magnetic Field	30 A/m	Complies	See Warning 10 on Page 3 of this IFU
(50/60Hz) magnetic field			

Manufacturer's Declaration – Electromagnetic Immunity						
Enclosure Port Immunity to RF wireless communications equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 499	Pulse modulation 18Hz	1.8	0.3	27

450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700- 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.						
a) For some services, only the uplink frequencies are included.						
b) The carrier shall be modulated using a 50% duty cycle square wave signal.						
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						
Immunity Test	IEC 60601 Test Level		Compliance Level		Electromagnetic Environment – Guidance	
Radiated RF	3 V/m		Complies		Not Applicable	
IEC 61000-4-3	80 MHz-2.7 GHz 80% AM at 1 kHz					
NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate Protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.						

^aField strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EVA Pro is used exceeds the applicable RF compliance level alone, the EVA Pro should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EVA Pro.

^bOver the frequency range 160 kHz to 80 MHz, field strengths should be less than 3 V/m

Contains Transmitter Module FCC ID: TFB-1004

















Contains Transmitter Module IC: 5969A-1004

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

SYMBOL DEFINITIONS

Symbol	Standard	Description
	Medical Devices Regulation 2017/745	CE Mark
	ISO 15223-1:2016	Device Name
	ISO 15223-1:2016	Serial Number
	ISO 15223-1:2016	Manufacturer & Date of Manufacture
	ES 60601-1:2005+A1:2012	Attention! See Instructions for Use
	ES 60601-1:2005+A1:2012	Type B Applied Parts
	N/A	CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician
	ASTM F203	MRI Unsafe Keep Away from Magnetic Resonance Imaging (MRI) Equipment
	ISO 15223-1:2021	Temperature Limits
	ISO 15223-1:2021	Humidity Limits
IP21	ES 60601-1:2005+A1:2012	Solid Particle Protection Level 2 (>12.5mm); Liquid Ingress Protection Level 1 (dripping water)
	ES 60601-1:20-05+A1:2012	Rated Input Power
	ISO 15223-1:2016	Authorized Representative in the European Community
	ISO 15223-1:2021	Medical Device
	IEC 60417	Waste of Electrical and Electronic Equipment (WEEE) To indicate that separate collection for waste electric and electronic equipment (WEEE) is required
	ISO 7000	Keep away from rain
	ISO 15223-1:2021	Do not use if package is damaged and consult instructions for use

mobile**CDT**
EVA Pro Instruction for Use

050-0009 Rev. B

January 2025