


gynocular
User Manual




gynius
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If you have any questions regarding Gynius products or services, please contact us at:
info@gynocular.com

Please refer to www.gynocular.com or email info@gynocular.com for the phone number of your local service representative.

Introduction:

Congratulations on your purchase of the Gynocular™, an innovation by Gynius. This manual contains the operation and maintenance instructions for your Gynocular™. Carefully read this document prior to operating the unit. Do not allow persons unfamiliar with the instructions to operate the Gynocular™.

Device Description:

The Gynocular™ is a hand-held colposcope, which provides a magnified visualization of the tissues of the cervix, vagina, vulva and anogenital area. It is used to evaluate these tissues and select areas for biopsy, without contacting the patient. The user is a medical physician, or a trained colposcopist.

The Gynocular™ is a colposcope with similar specifications to traditional colposcopes. The Gynocular has a 300 mm focal distance, 3-magnifications: 5x, 8x, and 12x. It is a handheld device that comes with a tripod-mounting clip that screws into a standard tripod enabling the medical professional to also perform colposcopy with the aid of a stand. The Gynocular™ uses high intensity LEDs for illumination, has a green filter, and is powered by a rechargeable lithium-ion battery. We also provide a charging base for the Gynocular™.

Indications for use (colposcopy):

The Gynocular is intended to provide magnified visualization of the tissues of the vagina, cervix and external genitalia. It is used to evaluate these tissues and select areas for biopsy.

Contra-indications (colposcopy):

There are no absolute contraindications to colposcopy. ¹



WARNINGS

- WARNING Users of this equipment should be thoroughly trained in the appropriate medical procedures. Furthermore, they should read and understand these instructions before performing any procedure. They should also read and understand the instructions for any other equipment used in conjunction with the Gynocular™. Failure to do so or misuse of the Gynocular™ may result in injury to the patient, misdiagnosis and/or damage to the Gynocular™.
- WARNING Keep all liquids away from electrical equipment to avoid the possibility of shock and instrument damage.
- WARNING The lamp is extremely bright. DO NOT stare directly into illumination lens when the Gynocular™ is turned on.
- WARNING Gynocular™ users should adhere to the operating conditions found in this manual. Otherwise, instrument damage may occur and/or operator/ patient safety may be compromised.
- WARNING The charger base is to be a minimum 1.5m from the patient - it should not be possible for the user to touch the charger base and the patient at the same time.
- WARNING For safety, the Gynocular's™ AC adapter should only be coupled to a grounded, 100-240 VAC, 50-60Hz hospital-grade outlet.
- Only charge the Gynocular™ with a Globtek WR9QE500LCP-N-MED 12V/0.5A power supply unit.
- WARNING Only use the supplied battery. The battery may only be charged in the unit.
- WARNING Do not expose the battery to heat or mechanical damage. Replace the battery after 2 years and dispose in a proper waste facility for electronic parts.
- WARNING No modification of this equipment is allowed. Do not modify the device.
- WARNING The Gynocular™ should not be used if broken, without functioning illumination or if dropped or cracked.
- WARNING Other gynecological vaginal exams are not allowed one day before the colposcopic examination. Vaginal medication should be avoided two days before the colposcopic examination. A colposcopic examination should not be performed during a menstrual period.

Gynius assumes no responsibility for any injury to anyone, or for any illegal or improper use of the Gynocular™, 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.



CAUTIONS


- CAUTION Occasionally inspect the charger's power cord for signs of cuts, abrasions or dents.
- CAUTION The Gynocular™ may not be used while placed on the charger.
- CAUTION The Gynocular™ should never be stored or operated in areas where it could get wet or could be exposed to any environmental conditions like extreme temperature or humidity, direct sunlight, dust, etc.
- CAUTION All service to the Gynocular™ must be performed by Gynius or by an authorized repair center.
- CAUTION There are no user serviceable parts in this unit or in its accessories. Any attempt to disassemble and/or repair this unit will result in voiding of the warranty.
- CAUTION Potential of mutual interference with other devices and remedies of electromagnetic compatibility. If interference is suspected, move the device or other equipment further away, or turn the device off to test if it is the source of interference. If interference is noted, physical separation is the best solution.
- CAUTION Do not immerse any part of the unit in cleaning solutions.
- CAUTION Do not touch optical or illumination lenses except as described in the Maintenance section of this manual. Only clean the device as advised in the Maintenance section of this manual.
- CAUTION The device should be placed on the charging station prior to first use to ensure full charge of the unit.
- Prescription for use:
 - CAUTION Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- CAUTION Please turn off the Gynocular™ after each use.
The image:  means refer to this User Manual.
- CAUTION The Gynocular™ is cooled by a heat sink which is visible as a silver/grey oval with the Gynocular™ logo on it. This is visible on both sides of the unit. To avoid overheating, verify that the heat sink is not covered while in use. Users should avoid touching the heat sink. If the Gynocular feels excessively hot, turn it off, and wait for it to cool down before using again. If problem repeats, turn off unit and contact service representative.

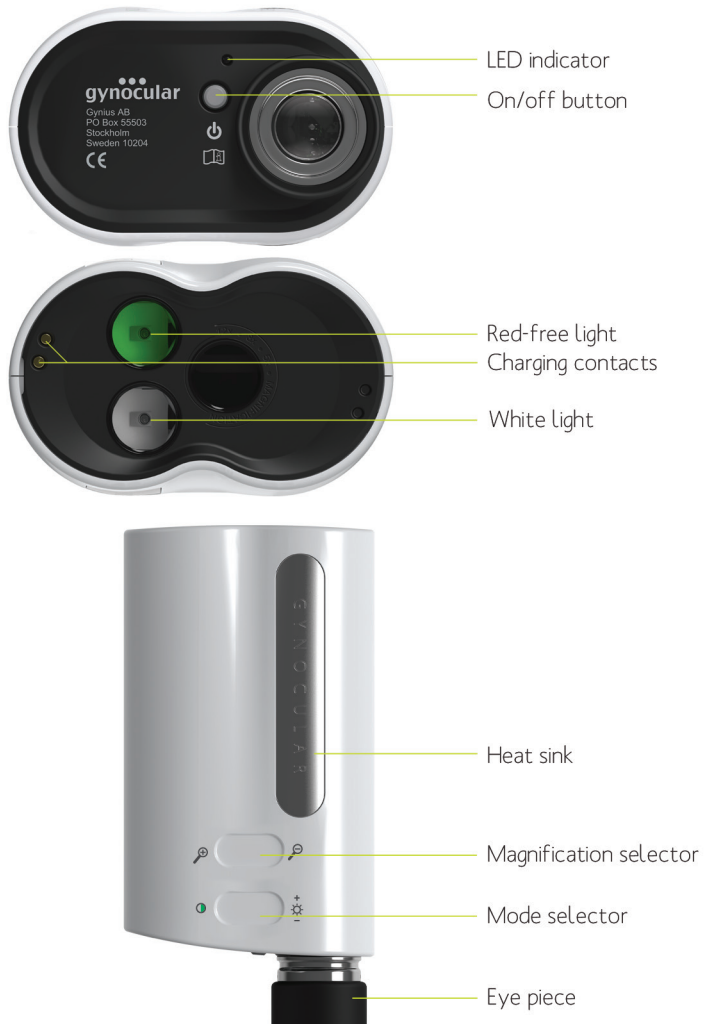
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Specifications

Item	Specification	Technical Data
Power requirements	Voltage Frequency Current Battery type Battery duration	90 - 264VAC 47-63Hz 0.18A @ 120 VAC; 0.36A @ 240VAC Lithium-ion 2-4 hours
Dimensions	Gynocular™	50mm x 83mm x 166mm
Weight	Gynocular™	Approx. 480g
Optics	Focal length Magnification Lens material	300mm 5x/8x/12x Glass
Operating environment	Ambient temperature Relative humidity	10C to +40C Maximum 80% non-condensing
Storage environment	Ambient temperature Relative humidity	-10C to +70C Maximum 80% non-condensing
Illumination	Lamp type Lamp life	LED >40 000 hours
Regulatory Compliance	CE	Complies with: IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), EN 60601-1 2006
Class/Type	EU USA	Class I Device Class II Device

LIST OF ACCESSORIES AND PARTS

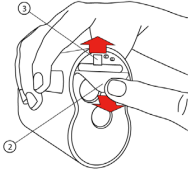
1. Gynocular
2. Tripod mounting clip
3. Charging base
4. Wall charger
5. Lithium ion battery



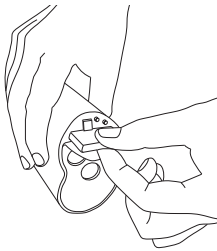
PREPARING DEVICE FOR FIRST USE:

Inserting and removing the battery

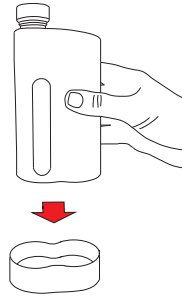
1. Locate the access point on the front of the device
2. Pull the rubber door open at the top and lift battery lock.



3. Hold the rubber door open while inserting the battery with its contacts on the left side at the back



Charging the device

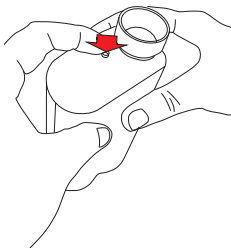


1. Plug the power adapter into the charging base
2. Plug the power adapter into the wall socket
3. Place the device into the charging base, front side down
4. The device should be charged prior to first use (full battery charge can take up to 2.5 hrs. The device is charging when the LED indicator is blinking.
5. The full charge has been reached when the LED indicator is a steady green light.

USING THE DEVICE:

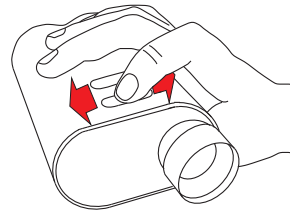
Switching on and off

1. Ensure that the battery is inserted
2. Ensure that the Gynocular's™ battery is charged
3. Press the on/off button on the back of the device



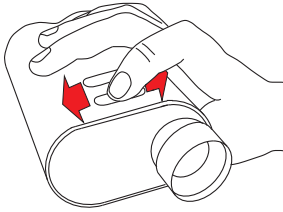
4. If the illuminator emits light from the front of the unit, it is on
5. Note that the unit always starts in 8x magnification and white mode

Selecting a magnification setting



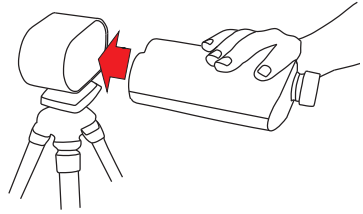
1. With the unit on, swipe your index finger gently and slowly across the mode selector
2. Swiping right to left will increase the magnification
3. Swiping left to right will decrease the magnification

Selecting a light mode

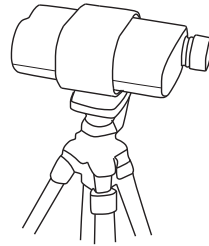


1. With the unit on, swipe your index finger gently and slowly across the mode selector
2. Swiping right to left will switch between white mode and red-free mode
3. Swiping left to right will increase and decrease light intensity alternately in white mode
4. Note that selecting red-free mode always resets the magnification to 12x
5. Note that if you change from red-free mode to white mode, the magnification will remain the same

Attaching the tripod holder



1. Locate the tripod screw insert under the tripod mounting clip
2. Screw your tripod's screw thread into this insert
3. Slide the Gynocular™ into the tripod mounting clip until it is in the middle of the holder



The following table can be used to understand what faults may be present with the Gynocular™.

Docked ¹	Power ²	Illuminator LED ³	Indicator LED	Indication/Fault and Action
No	On	On	Off	None. Normal condition
	On	On	Orange light flashing 1 second every 3 seconds	Battery getting low. Apprx. 7 minutes of battery life left. Recharge battery as soon as possible.
	On but switches off after 1 second.	On	Orange light flashes 3 times.	Battery too low for use. Recharge battery.
	On	Off	Orange light on	Over heat or circuit error. Make sure Gynocular is off. Wait for it to cool down before using again. If problem repeats, turn off unit and contact service representative.
	On but switches off after 1 second	Off	Orange light on for 500ms	Touch sensor error. Retry using the Gynocular. If problem repeats, turn off unit and contact service representative.

Docked ¹	Power ²	Illuminator LED ³	Indicator LED	Indication/Fault and Action
Yes	On	On	Off	No external DC connected to cradle; or no contact with the charging connections, or error in the controller PCB inside the Gynocular™.
	Off	Off	Off	Make sure external DC is connected and Gynocular is placed securely in charging station. If problem repeats, turn off unit and contact service representative.
		Off	Flashing green light	Charging in progress
		Off	Green light on	Charging finished
		Off	Orange light on	Temperature too high for charging (>45°C); or battery disconnected; or battery fault.
		Off	Flashing orange light	Internal fault; or intermittent battery connection. Contact service representative.

¹ Gynocular in cradle.

² On or Off as determined by the user's use of the power button.

³ Either Illuminator LED.

Cleaning Solutions

The solutions listed below are safe for cleaning the housing of the Gynocular™ if used according to the manufacturer's instructions for cleaning and in accordance with procedures detailed in the cleaning section of this manual.

- soap and warm water solution
- 70% isopropyl alcohol
- 10% mild bleach solution
- 10% Wescodyne

Gynocular™ Cleaning

Unplug the power cord from the electrical outlet prior to cleaning the charging base.

The Gynocular™ housing can be wiped down with a cloth dampened slightly with a mild solution of soap and warm water, making sure to get into the grooves of both the magnification and light selectors. Be careful not to allow the plug prongs of the charging base to get wet. Also be careful not to allow the lenses to get wet. Remember to clean the Gynocular™ after each use to avoid staining the device.

Lens Cleaning

Clean the lenses and glass covers with isopropyl alcohol or any commercial lens cleaner.

Repairs and service must be referred to an authorized Gynius Service Center. A technical manual is available upon request for qualified persons.

Technical Assistance

If you have an equipment problem that you cannot resolve, check www.gynocular.com to contact a Gynius Service Centre on normal business days. The Gynocular's™ serial number is located on the eyepiece. To locate it, unscrew the eyepiece from the main housing. The base charger serial number is located under the base charger. Service personnel will give you a Service Notification number. Please note this number on the outside of your shipping box. Shipping without a Service Notification number will not be accepted for delivery. Contact your medical clinic or Gynius sales representative for return or disposal instructions.

Gynius warrants the Gynocular™, when new, to be free of defects in material and workmanship and to perform in accordance with manufacturer's specifications for a period of five years from the date of purchase from Gynius or its authorized distributors or agents. Gynius will either repair or replace any components found to be defective or at variance from manufacturer's specifications within this time at no cost to the customer. It shall be the purchaser's responsibility to return the Gynocular™ to Gynius or an authorized distributor, agent, or service representative. This warranty does not include breakage or failure due to tampering, misuse, neglect, accidents, modification, or shipping. This warranty is also void if the instrument is not used in accordance with manufacturer's recommendations or if repaired by a non-authorized agent. Purchase date determines warranty requirements. No other express warranty is given. Gynius, or an authorized distributor, agent, or service representative will provide free recycling of the Gynocular™ unit at the end of its lifecycle. If you have any comments or questions regarding the Gynocular™, please contact us at info@gynocular.com.

Remember to submit the instrument registration/warranty card for warranty validation. Complete the information and mail the pre-addressed card to Gynius.

Complies with IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2
(2007), EN 60601-1 2006



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