

  
gynius



**A disruptive innovation that will revolutionize the field of women's health**

# Traditional and video colposcope

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# When and why to perform a colposcopy?

- ▶ To assess abnormal smear and and/or positive HPV test
- ▶ To exclude invasive cancer in a suspicious cervix
- ▶ To assess abnormal symptoms

# Diagnosis of cervical pre-cancers

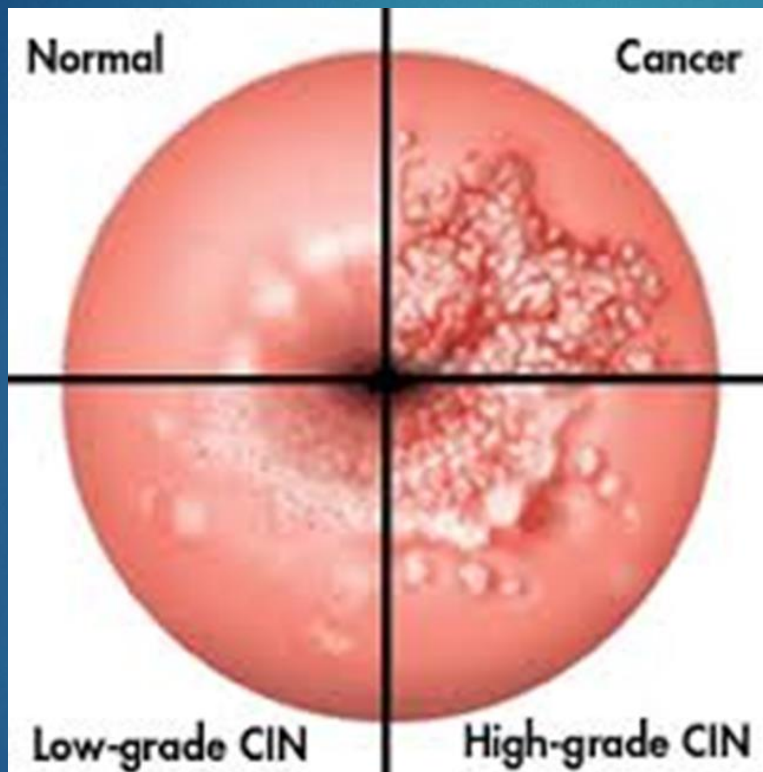


Image of cervical pre-cancer and cancer in different stages

# Major weaknesses with today's screening process

- ▶ Cervical cytology can fail to detect abnormal cervical lesions
- ▶ The HPV test is becoming the gold standard screening test, however many women will spontaneously heal their HPV infection
- ▶ Stationary colposcopes are expensive, heavy, cumbersome to use, stationary, and require an electrical grid



# So we developed: The Gynocular



# The Gynocular

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- ▶ Gynocular first clinically used in 2012
- ▶ First Gynocular unit sold in October 2013 in Sweden
- ▶ FDA approved in 2014
- ▶ Number of Gynoculars in use 395, including 26 new in November



# The Gynocular – Value Propositions

## ▶ Convenience

- Gynocular can be shared within departments and examining rooms, making a physicians job more convenient

## ▶ Clinical accuracy

- Gynocular has a proven clinical accuracy equal to the conventional stationary colposcopes

## ▶ Cost Value Props

- Gynocular is more affordable than than stationary colposcopes
- Strong reimbursement in most countries including US, can use existing CPT codes
- Shorter examination time due to easy to use equipment: enables more patients per day



# Designed for Today's Physicians

- ▶ Intuitive design
- ▶ Long battery time with standard mobile battery
- ▶ Light weight
- ▶ Easy to disinfect
- ▶ Developed in close cooperation with clinicians



# Gynocular - Technical features

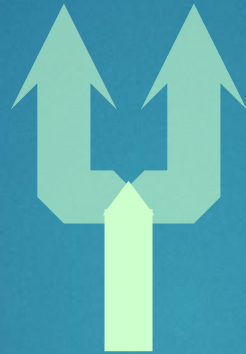
11

Color rendering

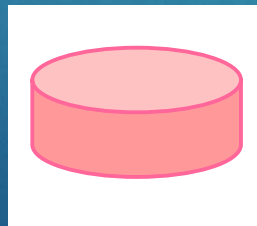
96-100 CRI

95 CRI

Effective light  
Intensity



DOF



# Technical Hardware

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## Hardware

- ▶ Light (CRI 95, intensity 12,000 Lux , effective 24,000)
- ▶ Programmable firmware (service notification & reset, Activity log)
- ▶ Expected life 5y: Mechanics + LEDs
- ▶ Drop tests (~100cm in the new version, 60cm before)
- ▶ Nokia battery one day of examination (1080mAh, )
- ▶ Designed for Fool-proof assembly
- ▶ 2.0 generation (Optics, electronics, illumination, mechanics)



# Certifications

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- ▶ ISO 9001:2016 certified
- ▶ ISO 13485:2016 certified
- ▶ Electromagnetic compatibility (EMC) certified to EN 60601-1-2: 2007.
  - ▶ Radiated RF Emissions
  - ▶ Radiated RF Immunity
  - ▶ ESD immunity (Electrostatic discharge)

## FDA approvals

- ▶ Gynocular - class 1 medical device, as colposcope.
- ▶ T2D Software - a Medical Device Data System (MDDS), under 21 CFR 880.6310.

## Software developer ITON/ICREA certifications

- ▶ CCHIT (The Certification Commission for Healthcare Information Technology)
- ▶ CMMI® Maturity Level 3 rating for the Software development (Capability Maturity Model Integration)

## Additional Approvals

- ▶ CE Marked (EU)
- ▶ Australia, Canada, China, India, New Zealand, Russia (pending), Thailand, various countries in Africa



# Made in Sweden

- ▶ Gynius maintains a Quality Systems program and follows Medical Device Reporting regulations. the design, packaging, labeling and manufacturing.
- ▶ Swedish quality
- ▶ The assembly, QC and packaging is done by Gynius, in Stockholm

# Securing Patient Data

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- ▶ Gynocular T2D is implemented with a high security process from the registration to every transaction of API calls between the mobile application and Cloud API. This involves a two stage process:
  1. Identity Security in CLOUD API
  2. Encrypting and Decrypting Data using AES 256 bit Algorithm
- ▶ Https protocol is used for secure communication

Telenor SE 21:27 31%

# GYNOCULAR T2D

Email

Password

Offline Online

Select Language

English >

Login

Forgot password ?

Telenor SE 21:28 31%

## Gynocular T2D

- New Patient
- Patient Search
- Schedule
- Referrals 157
- Our Website
- Demo Patient

Telenor SE 21:29 30%

Exit Elisabeth Wiks...

First name \*  
Gynocular

Last name \*  
demo patient

Date of birth  
3/25/1980

Age\*  
35

Phone number  
0046866442

Address  
Sjukhusvägen 1

Patient Details Consent History Colposcopy Exam Treat

Telenor SE 21:30 30%

Exit Elisabeth Wiks...

Examiner has explained to the patient of colposcopy examination procedure and treatment cervical lesions. Yes No

2. Examiner has explained to the patient of collection of samples for laboratory or histopathology or images of examinations findings for analysis and documentation. Yes No

3. I have also been informed that I can refuse the whole or part of the examination at any stage. In this event I have been informed about the possible medical/legal implications or consequences of loss of evidence and documentation. I have further been informed that this refusal will not have any impact on the quality of treatment provided. All this has been explained to me in a manner and language that I can understand. Yes No

4. Picture(s) of marks on the body for identification

Camera icon

Patient Details Consent History Colposcopy Exam Treat

Telenor SE 21:30 30%

Exit Elisabeth Wiks...

Abnormal bleeding  
N/A Yes No

Cytology year  
4/23/2014

N/A Benign LSIL  
HSIL AIC ASCUS

VIA+  
N/A Positive Negative

Smoker  
N/A Yes No

Current contraceptive  
None

Patient Details Consent History Colposcopy Exam Treat

Telenor SE 21:31 30%

Exit Elisabeth Wiks...

HIV status  
N/A Positive Negative

HPV vaccinated  
N/A Gardasil Cervarix

HPV test result  
N/A

Previous colposcopy date  
4/9/2014

Previous colposcopy results  
HSI

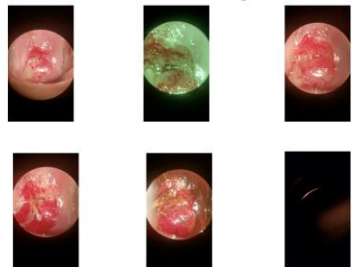
Previous treatment date

Patient Details Consent History Colposcopy Exam Treat

Telenor SE 21:31 30%

Exit Elisabeth Wiks...

Click to add image



Swede score

Vessels	2	-	+
Margins/Surface	1	-	+
Aceto uptake	1	-	+

Patient Details Consent History Colposcopy Exam Treat



# Building a unique global database

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- ▶ Built as a research data base/protocol – Big data
- ▶ Already 13.300 patients entered
- ▶ HPV incidence
- ▶ HPV in vaccinated/unvaccinated populations
- ▶ Results pap smear/LBC
- ▶ Biopsy results
- ▶ Swede score to support diagnosis and choice of treatment
- ▶ Referral network
- ▶ Evaluate performance of user
- ▶ Artificial intelligence image recognition?
- ▶ Possibility to expand database-
- ▶ Barcode HPV test-scanner-test result



# Log in to the web application

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The screenshot displays a web browser window with the following elements:

- Browser Tab:** Login | T2D
- Address Bar:** <https://www.gynocularart2d.net>
- Page Content:**
  - Image:** A white gynocular device with a black lens, labeled "gynius".
  - Sign In Form:**
    - Language:** English (dropdown menu)
    - Brand:** gynocular T2D
    - Email:** Input field with placeholder "Email"
    - Password:** Input field with placeholder "Password"
    - Forgot Password:** Link
    - Sign in:** Green button

The Windows taskbar at the bottom shows the Start button, search icon, and several application icons including File Explorer, Photos, HP, Chrome, and Firefox. The system tray on the right shows the time as 23:32 and the date as 13/06/2015.



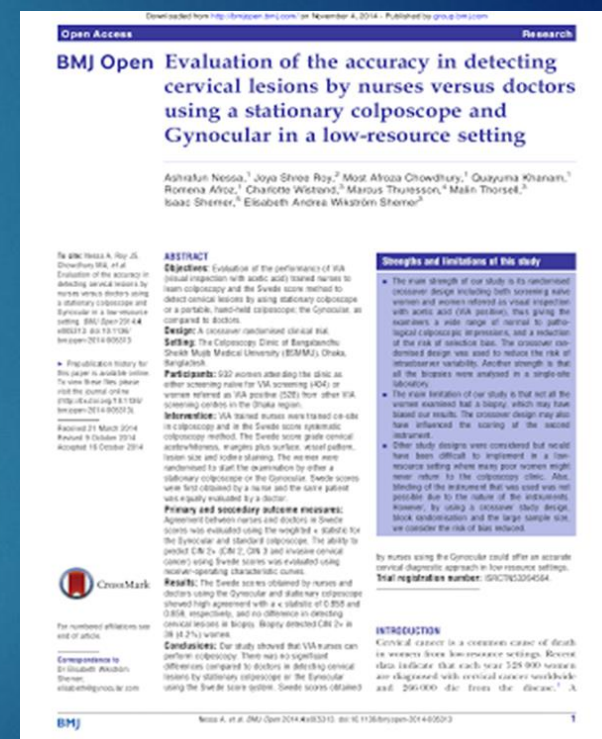
# T2D

- ▶ 2015-2016: 13,300 patients entered into T2D
- ▶ Logbook for colposcopists under training
- ▶ Quality control /review of users/feedback to organizations
- ▶ Unique GLOBAL research data base on pap smears, HPV strands in different populations....
- ▶ Global network of T2D users, sharing clinical problems
- ▶ Master trainers in different countries, referral doctors
- ▶ E-learning of triage

# Clinically validated in several studies

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- ▶ The quality of the examination was equally good when performed by use of the Gynocular™ or a stationary colposcope in detecting high grade cervical lesions.
- ▶ No significant differences when a colposcopy examination is performed by a nurse trained in colposcopy trained or doctor.
- ▶ Gold-standard colposcopy can be performed under essentially any conditions.
- ▶ Cervix examinations with the Gynocular reduced overtreatment with 70%.



“Gynocular has a great promise as a triaging tool for screen positive women in determining suitability for biopsy or immediate treatment and also decide on the nature of treatment “

# Ongoing research

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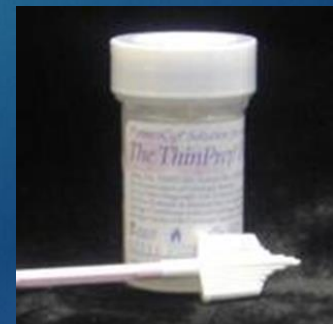
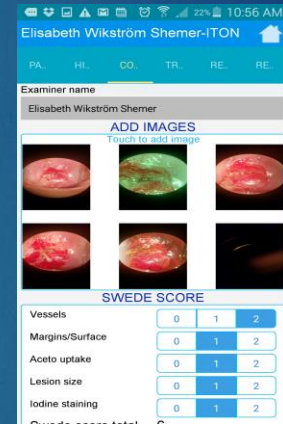
## Gynius Academic Research program

- ▶ Multiple site study Latin America and Africa
- ▶ Bern University: first PhD student
- ▶ Karolinska Institute; Health informatics masters on T2D
- ▶ EU network RESISTE application for Horizon 2020. EWS PI Swedish study arm- Cervical cancer screening in European women of low socio-economic status.
- ▶ Ghana: colposcopy training

# The Complete Package

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- ▶ Completes screening evaluation of positives of cervical cytology/HPV test
- ▶ Turnkey integration of hardware and software for large health groups and small clinics
- ▶ Strong reimbursement in most countries including US, can use existing CPT codes
- ▶ T2D software enables quality control and follow up of users/clinic data
- ▶ T2D enables networking and telemedicine in rural areas, saves time for the patient and the healthcare provider






- ▶ Documentation of sexual violence through secure app and webapplication
- ▶ Store up to 40 images
- ▶ Protocol to follow as to support health workers for correct documentation
- ▶ Includes section on forensic colposcopy
- ▶ In use in the US market since 2016



Telenor SE 10:22 75%



elisabeth@gynocular.com

Password

LOGIN

Forgot Password?

eTestify

- Definition of Sexual Violence
- New Patient
- Search Patient
- Schedule
- Referrals
- Our Website
- References

Consent Exit

If patient unable to provide informed consent, please follow institution or jurisdictional policies for obtaining legal consent.

3. Consent: I consent to a pregnancy test.  Yes  No

I consent to any medication provided.  Yes  No

I consent to Release of test kit of examination.  Yes  No

I Consent to any medication provided to me.  Yes  No

I consent to the above marked examinations.  Yes  No

If patient is under 12yrs. Of age or if patient is unable to give consent, guardian is suspected of incident, consent may be obtained from proper authority.

Save

Consent



Clear

OK

New Patient

Medical records number/Case number/Incident number

First name\*

Middle name

Last name\*

Date of birth\*

Age

Sex

Adult Female

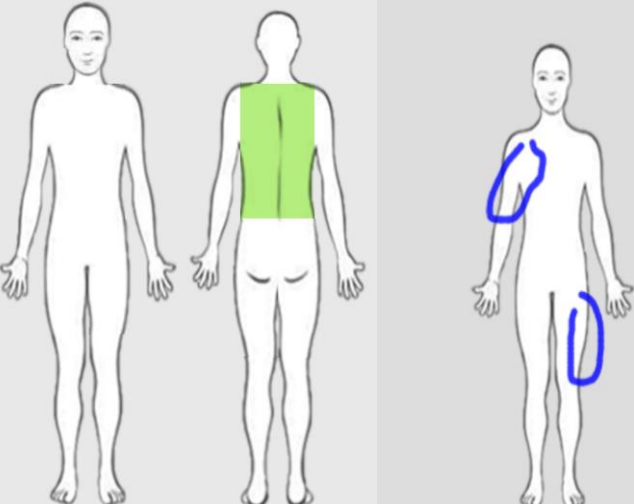
Address

New Encounter Book Schedule

Telenor SE 10:26 74%

General Exam Exit Body Chart Exit Genitalia Exam Exit

Note: Tap on the body parts to capture multiple pictures



Note: Tap on the body chart to mark injuries

Save

Telenor SE 12:51 61%

Genitalia Exam Exit

Genitalia examination findings

GENITAL INJURY SEVERITY SCALE(GISS)

Swelling: 0 1 2 2 2

Color Change(Erythema to contusion): 0 1 2 3 3

Tissue Break(Tear to abrasion): 0 1 2 3 4

Hymen and introitus: 0 0 2 3 4

Toluidine Blue dye uptake: 0 1 2 2 2

Sum Generated - 5

RESULTS CLASS B TYPE 3

Save

Telenor SE 21:32 30%

Elisabeth Wiks... Print

Select Doctor

Question

Refer

Telenor SE 21:32 30%

Save as PDF

Colposcopy patient evaluation form

Save as PDF

Colposcopy exam

Refer

Medical History General Body chart Genitalia Genit Consent Medical History General Body chart body chart Genitalia Genitalia chart Additional Light Test

History Colposcopy Exam Treatment Referrals

Colposcopy Exam Treatment Referrals Report

Colposcopy Exam Treatment Referrals Report

# In summary

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- ▶ Good for patients
- ▶ Good for physicians
- ▶ Good for clinics

