

# **LAY USER STUDY**

**Maybe Baby Mini-Microscope for Ovulation  
Cycle Observation**

**In Vitro Medical Device for Self-Testing by Lay  
User in Home Environment**

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## 1. PURPOSE

The purpose of the study was to evaluate the understanding of product instruction for use for untrained subjects (lay users) and to evaluate the performance of the device mini-microscope for ovulation cycle observation with lay users.

## 2. STUDY DETAILS

Study start date: 21st January 2016

Study results obtained: 4th February 2016

Locations: 1. Pecinci, Vojvodina, Serbia

2. Belgrade, Serbia

Participants: 30 participants divided into two groups

Time Frame: 2 hours per group

Participants were rated on comprehension of device instruction for use and evaluated for tasks which should be done for correct device usage.

Study staff rated participants on their success at understanding user guide and performing self-testing and evaluating other device features after subjects read product instruction for use. The rating scale was:

1. Successful in performing tasks correctly without assistance
2. Successful in performing after being referred to user instructions
3. Successful in performing after verbal assistance or review of part of user instructions
4. Unsuccessful - Incorrectly performed part of the testing or required intervention by study staff

## 3. ELIGIBILITY

Ages Eligible for Study: 18 Years to 45 Years

Genders Eligible for Study: Female

Education: All

Profession: All

## 4. STUDY RESULTS

### Participant flow

Started: 30

Completed: 30

Not completed: 0

Basic information on participants:

<b>Criteria</b>	<b>Number of participants per criteria</b>
Total number of participants:	30
Age:	
Under 18 years	0
Between 18 and 45 years	30
Over 45 years	0
Gender:	
Female	30
Male	0
Education level:	
Elementary	5
Middle	18
High	7
Region of Enrollment:	
Vojvodina, Serbia	15
Belgrade, Serbia	15

### Measured values:

<b>Measure description</b>	<b>Percentage of participants rated as &lt;=2 (Successful in performing after being referred to user instructions)</b>
Understand intended use of device	100
Understand device is not intended to be used as a form of contraception.	100
Understand period of day and under what conditions it is best to use device (consumption of food, beverages, tobacco, brushing teeth...)	100

Understand environmental conditions in which should use device (temperature, humidity)	100
Able to prepare sampling plate correctly (cleaning procedure)	100
Able to take saliva sample correctly	100
Able to place saliva sample correctly on sample plate	100
Understand procedure of proper saliva sample drying	100
Able to observe sample correctly (light switch on, image focus)	100
Able to interpret results correctly (fertile or infertile days)	100
Understand device has replaceable batteries	100
Able to replace batteries correctly	100
Understand batteries are recyclable	100
Understand environmental conditions in which should store device	100
Understand circumstances that may compromise results (pregnancy, breast feeding...)	100

## 5. CONCLUSION

Lay user study showed Maybe Baby mini-microscope for ovulation cycle observation is appropriate to be used as self-testing device by unskilled lay user in her home environment. Results showed that instructions for use provide all necessary information for correct device usage.

Belgrade,

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Optix Ltd.

Dragomir Stamenkovic

Mihailo Ceranic