



## Product Instructions



## PLEASE NOTE:

These instructions are updated from time to time and there may be a more recent version on our website: [www.yospermtest.com](http://www.yospermtest.com)

## YO PRODUCT INSTRUCTIONS

### ABOUT YO

Welcome to YO home testing. YO is the first FDA/CE cleared, Smartphone/PC/MAC based sperm test that not only reports your MOTILE SPERM CONCENTRATION (MSC), YO also provides you with a video of your sperm and your own YO SCORE that compares your results to thousands of other men. In addition the YO app has many fertility resources and information for both partners.

In normal intercourse a sperm has to move to reach an egg. So, it is important to test your 'supply' of MOVING sperm – YO does that.

Testing is easy with the YO app. Simply follow the testing instructions, checking off each step as you go and view the detailed animations. The test works by leading you through the entire process of preparing your sample and loading the YO slide. The slide is then inserted into the YO device. YO records a video of your sperm and then automatically analyzes it to see if you have  $\geq 6$  million motile sperm or less. You will also see your YO SCORE, a number between 10 and 90+ that shows how your results compare to thousands of fathers.

PLEASE NOTE: YO is a Smartphone/PC/MAC based home sperm test that provides a qualitative assessment of motile sperm concentration (MSC) in human semen. MSC is one aspect of a male semen examination. The YO Home Sperm test does not provide a comprehensive evaluation of a male's fertility status and is intended for over-the-counter, in vitro use only.

## **WHAT IS MOTILE SPERM CONCENTRATION (MSC)?**

MOTILE SPERM CONCENTRATION is the number of moving sperm cells in 1 milliliter of your semen. So, both sperm concentration and motility are considered. YO reports results as MODERATE/NORMAL MSC RANGE or LOW MSC RANGE based on a 6 million per milliliter threshold (cut-off). Results below 6 million will be reported as LOW MSC RANGE. Results equal to or greater than 6 million will be reported as MODERATE/NORMAL MSC RANGE. An explanation of your test results is displayed after your test is run.

## **WHAT IS MY YO SCORE?**

The YO SCORE is only shown when your results are in the MODERATE/NORMAL range of MSC. The YO SCORE shows you how your MSC compares to thousands of other men who have fathered children. YO SCORE results are reported in increments of 10 from 10 to 90+. You may be able to improve your YO SCORE over time based on following some of the information provided by YO. The YO SCORE is based on a large, global study of men's semen parameters conducted by the WHO and published in the 5th edition WHO Laboratory Manual for Examination and Processing of Human Semen.

## **YO INSTRUCTIONS FOR USE**

Relax... We understand how stressful this test can be and we've created an app that will lead you through the process with ease. If you want to view the process before testing, watch the HOW YO WORKS video on the app or go to our website: [www.YOpermTEST.com](http://www.YOpermTEST.com) to read all about YO.

## **IF YOU'RE RUNNING YO USING A SMARTPHONE**

- Download the free app at Google Play, the App Store or on the YO website: [www.yospermtest.com](http://www.yospermtest.com)
- Password protect your phone to insure medical confidentiality
- Charge your phone to at least 80% to avoid warning messages
- Insure that you have 100MB of free memory for YO video storage
- Do not use your phone during testing or the test may need to be re-run

## **IF YOU'RE RUNNING YO ON YOUR PC or MAC**

- Download the free app from the YO website: [www.YOspermTEST.com](http://www.YOspermTEST.com)
- Password protect your PC or MAC
- Insure that you have 100MB of free memory for YO video storage
- Do not use your PC or MAC during testing or the test may need to be re-run

## **PERMISSION QUESTIONS**

Any APP that requires the use of WiFi or your device's features such as sound, phone, etc. requires that you first authorize the use of these when running the APP. YO is not obtaining confidential information but is required to obtain your agreement the first time you run your test.

## **COLLECTING YOUR SAMPLE: RULES TO FOLLOW**

- Collect your sample by masturbation, directly into the sample collection cup provided in your YO kit
- Do not use condoms, lubricants or partners or this could affect results
- At least 1/8 teaspoon (less than 1 milliliter) of semen is required for testing
- Your sample can only 'sit' for one hour maximum so it's best to test right away

- Do not heat, cool or place your sample in the refrigerator – just let it rest
- Collect your sample when YO advises you and follow the instructions for testing right after collection
- For optimal results, do not have any sexual intercourse 2-5 days before YO testing
- Sample testing and sperm motility: Once you collect your sample, begin YO testing because your sample motility may decline after 1 hour. After you place the liquefaction powder into your sample as directed in the app, wait the 10 minutes as instructed but don't wait any longer than 30 minutes or your sperm motility may decline

### **WHAT IS INCLUDED IN THE YO KIT?**

- (1) YO DEVICE with power cable for Smartphone, PC or MAC that can be used for up to 50 tests
- Plastic cups for collecting your semen sample
- YO slides for sample testing
- Vials of liquefaction powder to make your sample runny
- Plastic pipettes for transferring the sample to the YO slide

### **WHY TEST AGAIN?**

Your sperm results can change over time. A "LOW" result today could be "NORMAL" in a month or two. If you receive a "LOW" YO result of MSC < 6M/ml OR if your YO SCORE is < 40 on your first test, you should consider re-running your test. If you have had a fever, spent a week in the hot tub...or if you are making positive lifestyle changes and just want to monitor your YO SCORE to see the improvements, wait two or three weeks and run another test. Remember, it only takes ONE sperm to fertilize an egg so you may be fertile even with a LOW result.

## **BEFORE YOU START: TESTING SUPPLIES**

- Prepare a white testing surface (a piece of paper will do)
- Remove the supplies from one of the envelopes in the YO kit
- Make sure the YO slide is removed from its wrapping and is face up
- Wear laboratory gloves if you are testing someone else's sample

## **HOW LONG DOES THE YO TEST TAKE? ~ 20 minutes**

- Sample Liquefaction (making your sample runny for testing): 10 minutes
- Filling the YO Slide with your sample: ~ 3-5 minutes
- Video capture, QC and analysis time: ~ 3-4 minutes
- Watching your YO video in awe: This could go on forever...

## **THE YO APP STEP-BY-STEP TESTING PROCESS**

1. Establish the YO WiFi and electrical connection to your Smartphone/PC or MAC
2. Collect your sample following the YO app instructions
3. Prepare your sample using the liquefaction powder supplied in the YO kit
4. Fill the YO slide with the supplied pipette following the YO app instructions
5. OK, START TESTING and in a few minutes you will see your YO results and video

## **AFTER TESTING: CLEAN AND SAVE YOUR YO TESTING DEVICE**


- The YO DEVICE can be used for up to 50 tests. After testing, clean the outside of the YO DEVICE with an Oxivir or alcohol wipe
- Between tests, place the YO DEVICE into a ziplock bag
- Throw away the used collection cup, slide and pipette after each test
- Wash your hands with soap and water after sample collection and testing
- Failure to follow these cleaning instructions could result in the transmission of infectious diseases such as hepatitis or HIV to others


## PERFORMANCE CLAIMS:

In clinical studies conducted with first-time users, the correct YO result, as compared to a laboratory instrumented method, was obtained 95% of the time. When conducted by professionals, correct results were obtained > 97% of the time.

Phone Type: Galaxy		SQA-V		
Galaxy		Low	M/N	Total
	Low	33	6	39
	M/N	1	96	97
	Total	34	102	136
PPA = 33/34 = 97.1%		95% CI: (84.7%; 99.9%)		
NPA = 96/102 = 94.1%		95% CI: (87.6%; 97.8%)		

## IMPORTANT NOTES AND WARNINGS:

 According to the World Health Organization (WHO), semen is considered to be a biologically hazardous material that can potentially transmit hepatitis and HIV.

 YO Home Test kit components that come into contact with semen should be treated as bio-hazardous materials. Clean with Oxivir wipes after use and strictly follow the storage and disposal instructions in this product insert.

## IMPORTANT NOTES AND WARNINGS








- YO home test kit components are intended for use by one person. Don't share the kit contents with anyone, including family members.
- Protective, powder free non-latex gloves are recommended for anyone testing someone else's sperm. Gloves are not required to test your own sperm.
- Condoms are not recommended for sample collection as they could impact the test results due to spermicidal agents that may be contained in the condoms.
- Samples collected during sexual intercourse are not recommended as test results may be adversely impacted due to the effect of vaginal mucous pH.
- Please note that in the presence of STD causing bacteria and viruses: e.g., *Neisseria gonorrhea*, cytomegalovirus (CMV), human papillomavirus (HPV), herpes simplex virus and *Chlamydia trachomatis* your potential sperm motility may be affected.
- YO may report results in LOW MSC RANGE in the presence of sexually transmitted diseases or infections but in the absence of such disease or infections your sperm could be in the MODERATE/NORMAL MSC RANGE.
- Please note that the use of the drug D-norgestrel (steroidal progestin) may affect your sperm motility count by lowering the count.
- Filling the slide inappropriately by not following the screen instructions may impact test results.
- The YO Home Sperm Test should not be used for contraception purposes or for post vasectomy testing.
- Perform YO Home Sperm testing in an environmental temperature of 60-85F (16-30 C). Avoid extreme cold and heat during testing. Do not heat or cool your semen sample.
- The YO Home Sperm test is intended for over the counter use. If used in a clinical laboratory or doctor's office, quality control testing should be performed according to federal, state and local requirements and regulations.
- YO is not cleared for use in evaluating the effectiveness of vasectomy surgery by the FDA.



## SUPPORT

YO support can be obtained by visiting our website: [www.YOspERMTEST.com](http://www.YOspERMTEST.com) or by emailing our support: [Support@YOspERMTEST.com](mailto:Support@YOspERMTEST.com)

## SYMBOLS USED IN THE SYSTEM

Symbol	Description
	CE mark. European Conformity
	Consult Instructions For Use
	IMPORTANT: Read and understand user guide and all precautions before using
	Manufacturer address
	Manufacturer's Batch Code
	Expiration Date
	In Vitro Diagnostic Device
FDA	FDA Cleared: U.S.



MES Medical Electronic Systems LTD



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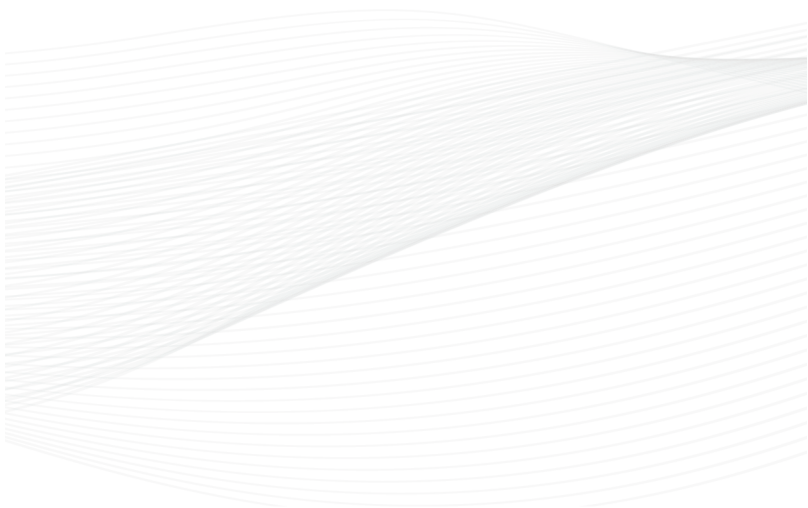
## FCC Warning Statement

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. 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 or more 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.

FCC Radiation Exposure Statement  
The antennas used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located for operating in conjunction with any other antenna or transmitter.





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