



## **Comparison of OvaCue<sup>®</sup> Fertility Monitor and the OvWatch<sup>®</sup>**

The following provides a brief comparison of Zetek's Electrolyte Method<sup>™</sup> embodied in the OvaCue<sup>®</sup> Fertility Monitor, with the Health Watch System OvWatch. Zetek's Electrolyte Method relies on changes in the electrolytes in saliva to predict ovulation (the key indicator of fertility) up to seven days in advance. Changes in the electrolytes in vaginal mucus are monitored by the OvaCue to confirm ovulation. Comparisons can be grouped into the following categories:

### **I. Accuracy**

Although variations in electrolyte content of perspiration during the menstrual cycle have not been as thoroughly documented as they have in saliva, changes in levels of NaCl content in relation to the ovulatory process are entirely plausible in the light of other known research. In fact, anecdotal folk medicine has held for a long time that the taste of a woman's skin surface was linked to fertility. The problem with monitoring perspiration scientifically for this purpose has been to find a reliable way to quantify the phenomenon and to bypass the many sources of variability not related to reproductive endocrinology.

The scientific basis for the OvWatch is traceable to the breakthrough work done by Zetek Scientific Director Ranjit Fernando that connected the reproductive hormone-ACTH-aldosterone-androstenedione axis to salivary electrolytes (and therefore to electrolytic characteristics of perspiration). Dr Fernando showed the relationship between the pre-ovulatory surge in estrogen and these end-organ phenomena in his revolutionary research published in *Human Reproduction*<sup>1</sup>.

The makers of OvWatch claim to have solved the problems of measurement and reliability. A study was performed at Duke University that supports the application of the manufacturer to 510(k) status as substantially equivalent to ClearPlan Easy Fertility Monitor, Cue (not Ovacue) Fertility Monitor, and Tcoyf Fertility Software. One hundred women participated in the non-randomized study. Although the number of cycles analyzed is not specified in the application, the implication is that each woman contributed one cycle for a total of 100 cycles.

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<sup>1</sup> "[Physiological Mechanisms Associated with Ovulation Prediction Using the Cue Fertility Monitor](#)", by Ranjit S. Fernando, Ph.D., Jennine Regas, M.S., and George Betz, M.D., Ph.D., *Human Reproduction* Volume 3 No. 4, 1988

In contrast, Zetek's initial Phase One study reported results for 103 cycles, continuing research under Phase Two and other studies totaled over 2000 cycles. Each of these successive programs substantiated the earlier results as well as expanding the potential usefulness of the Cue technology, especially into diagnostic and therapeutic applications.

The Duke study very properly used the 'gold standard' serum LH surge and peak to define the day of ovulation. Unfortunately, however, efficacy of the OvWatch technology was corroborated using outdated or minimally useful methods, i.e., the basal body temperature (BBT) and urine LH monitoring. BBT monitoring is now only used to confirm or identify ovulation retrospectively, not to predict. Urine LH monitoring alone has been shown by many investigators to provide a minimal window of predictive information. In comparison, Zetek studies correlated efficacy results with more reliable ovulatory markers, such as follicular ultrasound scans and serum LH monitoring, as well as a oral and vaginal electrolyte levels, urinary LH, BBT, and cervical mucus observations.

Perspiration is more vulnerable than saliva to physiological and environmental factors. The website *WrongDiagnosis.com* discusses 407 medical conditions that can cause sweat symptoms, including anxiety, anger, menopause, hypoglycemia, certain medications, illness, hyperthyroidism, stress, and 399 more. The mechanisms of perspiration are subject to conditions of temperature and humidity, illness, diet, hydration levels, etc. that do not affect the reproductive cycle but can affect the readings of the OvWatch.

The effects of stress on the ovulatory process are recognized. Some major forms of stress, both physiological and psychological, affect all methods of ovulation monitoring because they affect the ovulatory process itself. These would include athletic stress, psychological stress due to life circumstances (including diagnosis of infertility, which has been identified as a major stressor equivalent to diagnosis of a major illness like cancer or heart disease), and physiological stress. These stress factors will effect the reproductive cycle, but will not be recognized by the OvWatch.

Clomiphene citrate (CC) is a first-level infertility therapy that can cause sweat symptoms. Its effect on Zetek's salivary monitoring has been carefully documented and published in the peer-reviewed journal *Fertility and Sterility*<sup>2</sup>. Other reproductive conditions that affect perspiration include perimenopause and polycystic ovarian syndrome (PCOS). Again, while undetectable by perspiration monitoring, the patterns of Cue readings in these conditions have been defined and documented. In fact, use of Zetek's technology as a screening method for PCOS and three other ovulatory disorders was the subject of a successful Phase I study that will be continued when resources for the project are available.

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<sup>2</sup> "[Prediction of Ovulation with the use of Oral and Vaginal Measurements during Treatment with Clomiphene Citrate](#)", by Ranjit S. Fernando, Ph.D., Jennine Regas, M.S., and George Betz, M.D., Ph.D., *Fertility and Sterility*, March, 1987

## **II. Convenience**

According to the OvWatch User Reference Manual, the OvWatch must be worn everyday, but cannot be worn during times of possible accumulation of moisture on the skin, including during exercise or heat. This causes a conflicting requirement for women in that they must wear the watch everyday, but can not wear it during normal activities, or potentially even in hot summer months. The OvWatch is just that, a watch, not a dedicated fertility monitor. Many women do not want to wear a conspicuous and bulky watch everyday to monitor their fertility. The OvWatch precludes them from wearing a watch they may rather wear and practically advertises the fact that they need to monitor their fertility, a subject most women would rather keep private. Additionally, the watch must be worn rather tightly, such that it cannot move on the arm and has been reported by users reviewing the product on-line to leave a gooey gel residue on the arm.

## **III. Cost**

The retail prices of the OvWatch and the OvaCue are \$229 and \$298, respectively. OvWatch requires the purchase of additional sensors at a cost of \$39 per month. According to Amazon.com, total packaged street price (including three sensors) is \$288. The OvaCue sells for \$298 and no additional purchases are required (although this is expected to change upon launch of the new OvaCue, which will have a substantially lower target retail price). Currently, retail cost for 6 months use of OvaCue is \$298, while the retail cost for six months' use of OvWatch is substantially higher at \$463.

## **IV. Advance Notice of Ovulation**

Advance notice of ovulation is crucial for monitoring fertility, independently of a consumer's particular fertility goals. For avoiding pregnancy, a couple must know well in advance when ovulation will occur, so that they may abstain during all six days of the fertile window<sup>3</sup>. For couples seeking to achieve pregnancy, advance notice is important to plan for the timing of intercourse or for the scheduling of in-vitro fertilization or artificial insemination. The OvaCue offers a significant advantage by giving up to 7 days advance notice of ovulation, more than OvWatch (which claims 4 days advance notice) or any other ovulation prediction method.

## **V. Applicability**

OvWatch is more limited in its application than the OvaCue, which will work for women experiencing cycles up to 99 days in length. According to caveats published in the Ov Watch User Reference Manual:

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<sup>3</sup> The OvaCue is not approved by the US FDA as a contraceptive.

- “Women with regular monthly cycles lasting between 24 and 35 days are suitable candidates...” *These women rarely need an ovulation monitor of any kind*
- “Women whose menstrual cycles are anovulatory might get misleading results from this device.” *Anovulatory cycles are readily identified with the OvaCue method.*
- “The watch is designed to work on naturally ovulating women...” *The OvaCue works very well with women undergoing ovulation induction using clomiphene citrate and other ovulation inducing medications.*

## **VI. Support**

All customers of Zetek are welcome to call a toll-free help-line at any time during the first year of use of the OvaCue. Questions about the specific use of the monitor or general questions about fertility and reproductive science are answered by experienced staff at no cost to the consumer. Zetek’s trained fertility experts also are available to track a woman’s cycle every day if necessary, to identify the proper time for her to attempt conception and to notify her of possible ovulatory disorders. OvWatch offers no such customer support.

## **VII. History**

Zetek has been helping couples meet their fertility goals since 1983. For almost 25 years, Zetek has pioneered the way in electronic ovulation prediction and fertility monitors. Over 17 articles about Zetek and the Electrolyte Method have been published in noted scientific and peer-reviewed journals, and over 2,000 cycles of Cue data have been collected and analyzed. These articles document extensive independent scientific research conducted with Zetek’s methodology. Also during that period, two NIH funded studies were completed at the University of Colorado Health Sciences Center, which proved the efficacy of Zetek’s method and determined that the OvaCue is 98% accurate in predicting and confirming ovulation, i.e., determining the optimum time for intercourse or insemination to achieve conception.

## **VIII. Approval**

The OvaCue and the Electrolyte Method have been approved for use as an aid to conception by the U.S. FDA. The method and device have also been approved by the Vatican as consistent with the teachings of the Catholic Church and finally, the Electrolyte Method has been recommended by numerous doctors specialized in the field of reproductive medicine. The OvaCue has also been recommended by thousands of couples who have conceived using the OvaCue when they were unable to conceive using other methods.

## **IX. Conclusion**

The OvaCue has numerous practical and scientific advantages over the OvWatch. Zetek's method also has numerous advantages over any other existing method of predicting or confirming ovulation. For a complete discussion of the advantages of the Electrolyte Method, and the OvaCue<sup>®</sup> Fertility Monitor, please visit Zetek's website at [www.ovacue.com](http://www.ovacue.com) or call 1-800-FOR-CUES (800-367-2837).

OvWatch is a registered trademark of Health Watch Systems, Inc. OvaCue is a registered trademark of Zetek, Inc.