

Clinical Tests on BABY-COMP® and LADY-COMP®

- 1. Trial of contraceptive effectiveness of Lady-Comp® / BABY-COMP®; test of randomly chosen 510 women and 3332 (over 13 cycles usage).**
Field study published by the Polish Gynecological Society.
Results: User Pearl-Index 0.64. (Original in German)
Under direction of Prof. Ewa Markwitz, 2010
- 2. Medical Evaluation, EG-Instruction 93/42 EWG und MEDDEV.2.7.1.**
Results: 'very high degree in Method-Security, which clearly stands out from competitive devices'. (Original in German)
Dr. Andreas Marx – ClevaMed, Sept. 20th, 2007
- 3. Trial of contraceptive effectiveness of Lady-Comp® / BABY-COMP®; test of 686 women and 12.213 cycles over 24 month.**
Field study in Switzerland, Germany and Mexico.
Results: User Pearl-Index 0.7.
Düsseldorf 1998, Dissertation Bachhofer, Prof. Freundl, Frank-Herrmann, Prof. Godehardt, Klemm
Advances in Contraception 1998; 14: 97-108; Prof. Freundl, Frank-Herrmann, Prof. Godehardt, Klemm, Bachhofer
Birmingham 1997, Prof. Freundl
- 4. Test on women sterile for 3 – 8 years.**
BABY-COMP® compared with clinical testing.
Results: 100% match on luteal deficiency, anovulatory cycles and pregnancies.
Clinical found 86% Ovulation's, BABY-COMP® 80%.
Sassari 1997, Prof. S. Dessole, Fadda, Rosas, Scapinelli, Inaudi, Ambrosini
- 5. Clinical testing and comparison with BABY-COMP®.**
Results: Perfect match between clinical findings and fertility indications of BABY-COMP®. (Original in German)
Erlangen 1994, Prof. Wildt, Fertilität 1992, Nr. 8, Pages 66-67
- 6. Clinical Test and research on Hormone- and Temperature shifts.**
Results: They do correlate and there is BABY-COMP® that might improve reliability, acceptability and application of BBT in fertility investigation.
Amsterdam 1992, Prof. Martinez, v. Hoof, Schoute, v.d. Meer
- 7. Test on fertile women. Compared with clinical testing.**
Definition: 6 Days are fertile.
Results: Lady-Comp® found temperature shift in each cycle. Number of fertile days 11.1 +/- 3.
Length of cycles 25-35. No pregnancy on 'green' days.
Barcelona Congress 1992, Prof. Freundl, Bauer, Bremme, Döring, Frank-Herrmann
- 8. a) Test on preciseness of temperature readings.**
Results: Temperature readings highly precise $p < 0.01$. (Original in German)
b) Test on prevention compared with clinical testiness.
Results: No unwanted pregnancies on 'green' days. (Original in German)
c) Test on planning.
Results: 2 out of 5 conceived already during the test.
Rhodos 1988, Prof. Freundl, Frank-Herrmann, Toncaboni

Published reports

- 1. Dr. Hubertus Rechberg: Contraception and Baby-planning with Lady-Comp® and BABY-COMP®**
Congresso della Societa Italiana della Contraccezione, June 16-18th, 2005 Lettura BABY-COMP®
- 2. Sheelah Kolhatkar: Orgasmatron shows up: High-Tech-Rhythm**
New York Observer, Juni 25, 2004

Certifications

- 1. Medical Product, Directive 93/42/EEC, January, 2009**
Quality Management, Medical Device, Directive 93/42/EEC
Quality Management, Voluntary participation in regular monitoring EN ISO13485:2003 + AC:2007.
- 2. Certification EMV EN60601-1-2**
March 12th, 2007 LADY-COMP® / March 19th, 2007 BABY-COMP® / July 10th, 2007 pearly®
- 3. Certification of Production**
ISO9001: 2000 / ISO14001: 2004 / Environmental Assessment Bavaria, December 16th, 2005
- 4. FDA, January 2005 Office of Device Evaluation (ODE)**
as an aid in ovulation prediction



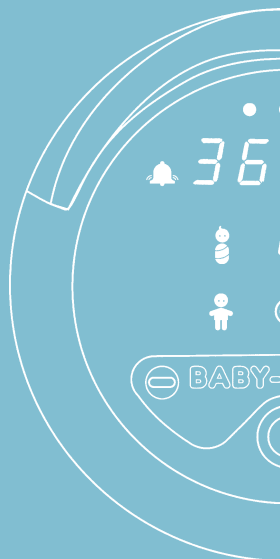
Quality Management
Medical Device
Directive 93/42/EEC



Quality Management
Voluntary participation in regular
monitoring
EN ISO13485:2003 + AC:2007

...the safe
fertility computers
for over 25 years

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