

## Safety & Reliability Confirmed by Prof. Freundl in Dusseldorf

### Has Ladycomp / Babycomp been investigated by specialists in this field (about safety)?

Yes, Babycomp and Ladycomp were submitted for several independent clinical tests and studies. 1998 contraception safety of Babycomp and Ladycomp was tested with 686 women over 2 years; the result: Pearl-Index 0,7.

The first time Prof. Dr. med. G. Freundl from Germany tested Babycomp, it was on 20 women in the course of 199 cycles. Here is his summary of this pilot study to determine the fertile days in a woman's cycle.

Babycomp for natural family planning: Many couples are looking for a method of family planning that does not involve the use or intake of artificial substances. They try to judge the cyclic fertility of the woman by observing body signals and adapt their sexual behavior (intercourse or no intercourse) in their efforts to avoid or plan a pregnancy. The so-called natural family planning methods, which in the past could only provide women with relatively unreliable information, now offer very reliable possibilities to achieve this aim.

With regard to reliability we can recommend two methods at the present time: first, the basal body temperature method and second, the symptothermal method. The former establishes information about a woman's fertility or infertility based on the observation of the cyclic course of the woman's basal body temperature. In addition to analyzing the basal body temperature, the latter examines the mucus in the neck of the womb. Both methods require the user to learn and adhere to very specific rules developed in the course of long-term research.

The strict observance of these rules ensures that the method reliability corresponds to 0.5 and 1 on the Pearl Index with the actual reliability in use amounting to between 1 and 2.8 on the Pearl Index. In prospective research to establish the reliability of the aforementioned methods, we, at the University of Dusseldorf, were able to confirm these figures as part of a research project on natural family planning.

Many women, however, felt that learning and applying the appropriate rules on a daily basis was too much trouble, too time-consuming and too complicated. With this in mind microcomputers were developed and programmed to contain the rules for the temperature method. A sophisticated evaluation program enables them to display the statement fertile or infertile on the appropriate days.

Babycomp is such a device. We have tested Babycomp on 20 women in the course of 199 cycles. The results proved that this device provides many women with valuable assistance in their efforts to increase their knowledge of their individual cycle and assess their level of fertility. Naturally it does not eliminate the need for abstinence if a pregnancy is to be avoided.

The device also takes a great number of particular situations into consideration in its program. Compared with other natural methods requiring considerable learning, I consider Babycomp to be a very good and highly recommendable alternative for couples who feel at home with modern appliances and prefer to limit interventions in the body functions to a minimum. It goes without saying that a computer is only as good as the theory that it is based on, in this case the basal body temperature method.

The fact that it is however better in its overall results can be explained by the reduction in human error when using this device. I would therefore like to see this device widely used. It will certainly live up to its expectations. Naturally it is nevertheless important to recognize the limitations of technology and to consult an experienced doctor or counselor in the event of uncertainty.

Signed by Prof. Dr. G. Freundl.  
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How reliable is Ladycomp/Babycomp in comparison with other methods of contraception?  
The reliability of a method of contraception is expressed in the medical profession by the Pearl Index. The Pearl Index indicates how many unwanted pregnancies occur in 100 user years. A contraceptive pill with a Pearl Index of 1 means that if 100 women use this pill for contraception for one year, one woman will nevertheless get pregnant during this time.

The Pearl Index of a specific method of contraception is determined by means of large-scale surveys. The scope of such surveys requires the observation of approx. 20,000 cycles.

The development of Ladycomp/Babycomp was able to benefit from the fact that thousands of women had already been using the temperature method for years and had therefore been compiling their charts and data it was possible to save this information on magnetic disks together with data concerning exceptionally difficult cycles from text books and the archives of research institutes.

The Ladycomp/Babycomp program was required to evaluate these cycles again and again. If it made mistakes, it was corrected until it was able to evaluate all cycles accurately.

Up to January 1996 the Ladycomp/Babycomp program was able to prove its reliability by accurately evaluating approx. 700,000 cycles for approx. 20,000 users. The device has therefore fulfilled the requirements of the Pearl Index already ten times over.

Clinical research led by Prof. Dr. med. G. Freundl in Dusseldorf confirm the reliability of this device (see answer to question 2).

If Ladycomp/Babycomp shows "green", the likelihood of a pregnancy less than when taking the pill (Pearl Index = 0.6- 0,7).