

**Summary of the Retrospective Study
of the Reliability, Acceptance and Safety of the
Miniature Computer BABY-COMP®/LADY-COMP®
in Natural Family Planning**



**Summary of the Results
from the Department
of Gynecology and Obstetrics
of the Municipal Hospital
of Düsseldorf-Bernrath.**

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**Dissertation for the Degree of
Doctor of Medicine of the Medical Faculty
of the University of Düsseldorf**

submitted by

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1997

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According to a survey carried out by the Emnid Institute, there is a common desire among the majority of women and their partners for a safe, simple and risk-free method of contraception. BABY-COMP® and LADY»-COMP® have a pearl Index of 0.7. All that is required is the oral measurement of the BBT every morning. Furthermore, there are absolutely no side effects. Even the excretion of hormones into the water cycle, which occurs when taking the pill, is avoided. All this is possible thanks to high technology, computer programming and state-of-the-art scientific knowledge.

Over a period of more than two years, 686 users in Germany, Switzerland and Mexico were questioned about their experiences with BABY-COMP®/ LADY-COMP®. The women came from a broad range of income and vocational groups. The majority of the users (people who try it) worked in the medical or paramedical sector. The average menstrual cycle length amounted statistically to 29 ± 5.4 days. Unusual cycles were also represented in the survey. Correspondingly, there was a considerable fluctuation in the days identified as being fertile. The computer program proved to be reliable and displayed effectively the shortest time span that can be considered safe. The key result: 0.7 pregnancies per 100 women in one year.

The user sample was put together randomly, the menstrual cycles were arbitrary. 86 % of the women had previously taken the pill. Obese women proved to be twice as likely to have irregular cycles. Partners showed an increasing tendency to be in favor of using the device. There was a general acceptance of the method. According to the statistical process illustrated by the Kaplan-Meier Survival Curve, the long-term stability is high. Long-term use of BABY-COMP® and LADY-COMP® results in constant safety.

90% of those questioned would recommend the device to others. This makes the behavior methods a viable choice for those who, up to now, have found them to be too time-consuming and unreliable. Now it is up to you to recommend this new but proven method to your patients and other interested parties. Upon request, we would be glad to send you the complete study comprising 80 pages.

*Yours faithfully
Dr. H. Rechberg*



1.1 Participants

The data of 686 users from Germany, Switzerland and Mexico were evaluated for the period from 1992 to 1995 (fig. 1).

The average usage time was 16 months. In contrast to previous research (Toncaboni, 1992), the users questioned had not received instructions about the BBT* method, its physiological background or its application. Most of the women had heard about the minicomputer from a friend, ordered and received the product information from the manufacturer.

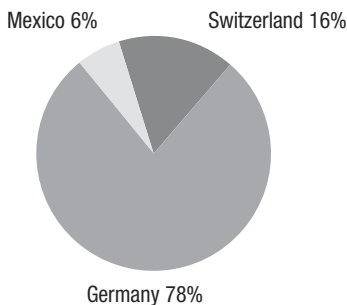


Fig. 1: Overview of users taking part from the various countries (n= 686).

*BBT = Basal Body Temperature (basic temperature of the body)

1.2 BABY-COMP®/LADY-COMP®

The BABY-COMP® and LADY-COMP® devices were developed as part of a collaboration between information scientists, designers, social scientists and gynecologists.

The concept and objective of this invention were:

- to facilitate contraception / family planning using the BBT method*, to facilitate the keeping and tracking of temperature graphs and their evaluation.
- to eliminate the interpretation errors which frequently occur with inexperienced users.
- to create a safe, non-invasive alternative to other methods of contraception and family planning.

In this context, a futuristic-styled device was developed in the form of a 3 cm high disk with a diameter of 14 cm, and weighing 200 g. A detachable temperature sensor with a spiral cable is integrated into the side of the device. The BABY-COMP®/LADY-COMP® device has a temperature display, a clock and alarm function and three lights in the colors of the traffic lights: red, yellow and green.

The user is awoken by an acoustic signal at the time she set the alarm. This must be within a time span of 3 hours before or 3 hours after the previous set time on the day before. The sensor is placed under the tongue. A button is pressed to start the temperature reading. Within 30 seconds, the sensor takes the user's temperature and automatically stores the data in the computer.

*BBT = Basal Body Temperature

1 Material and Method

The computer is equipped with an algorithm* of the temperature method. This calculates whether each day is a fertile (red), infertile (green) or uncertain (yellow) day. The data the computers use to differentiate between fertile and infertile days are based on a few biological facts underlying the female monthly cycle.

- Every woman ovulates only once in each cycle. An egg will grow in the right ovary one month and in the left one the next month, always alternating.
- After ovulation, the egg can be fertilized for a maximum of 18 hours.
- On the rare occasion of two or more ovulations, they will occur within 24 hours. The maximum possible timeframe for fertilization after ovulation can therefore be accurately determined.
- The same is true for the time before ovulation: after intercourse, male sperm will remain active and fertile in the female body for a maximum of 120 hours (five days).
- This means that there are six days in every cycle when a woman can get pregnant: five days before ovulation and on the day she ovulates.

The more information the computer collects, the easier it is to narrow down the number of fertile (red) days thanks to the computers integrated learning software.

* algorithm = calculation procedure / BBT= Basal Body Temperature

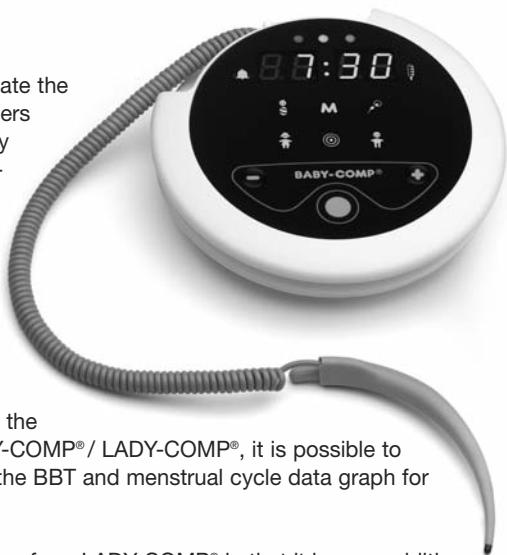
1 Material and Method

In order to accelerate the learning phase, users have the possibility to enter past menstruation cycle data into the device before using it the first time.

To analyze and monitor the menstruation data and the efficiency of BABY-COMP® / LADY-COMP®, it is possible to make print out of the BBT and menstrual cycle data graph for the last 120 days.

BABY-COMP® differs from LADY-COMP® in that it has an additional integrated cycle and planning-statistic displaying the optimum day for conception, hormonal imbalances, and a prognosis of the sex of the offspring.

The prognosis is indicated before ovulation and displays after fertilization the expected sex of the offspring. The integrated pregnancy test will detect initial indications as early as after 5 days, if the woman has conceived. BABY-COMP® will then calculate the offsprings expected date of birth based on the day of conception.



2 Results

2.1 General Data

There were 686 completed questionnaires available for evaluation. The study took into account a total of 10 975 menstrual cycles of the users. BABY-COMP® / LADY-COMP® was used by 633 women as contraception for 10 601 menstrual cycles and months.

The mean age of users was 27.9 years. The average age of the Mexican women was 26.6 years, making them younger than the German and Swiss women whose average age was 28.

The average cycle length for 419 cycles containing all necessary menstrual cycle data was 29.2 ± 5.4 days.

Of the 686 users, 392 had no children (57.1%), 160 had one child (23.3%), 89 women had 2 children (12.9%) and 44 women (6.4%) 3 or more children. One woman did not supply information.

German and Swiss women had an average of 0.7 children, whereas the Mexican women had 1.1 children.

2 Results

In all countries, there was a similar distribution of the education level and their professional groups. However, the largest number of users worked in the field of medicine and paramedicine (table 1).

Five hundred and sixty-nine women (83 % of users questioned) used the temperature computer exclusively for contraception; of this group, 7 women who did not have a regular menstrual cycle due to lactation were excluded from the evaluation of the contraceptive reliability of the device.

A total of 46 women had used the device exclusively for conception; 71 women (10.3%) had used it for contraception, as well as for conception.

In this study, BABY-COMP® / LADY-COMP® was used for contraception by 633 women during 10 601 months. The sample included 493 Germans with 8284 months, 104 Swiss with 1991 months and 36 Mexicans with 326 months.

2 Results

Activity / Profession	number
Housewife	174
Worker	12
Hotel, agriculture, truck driver	8
Paramedical, social activity	82
... of whom nurses	40
Non-medical practitioner	7
Flight attendant	7
Office worker	120
Cosmetic and manual worker	22
Professional, managerial employee	62
Free-lancer	16
Teacher, social worker, psychologist	40
Graphic artist, designer, artist	26
Doctor, biologist	9
Business economist, information technologist and other engineers	12
Lawyer	4
Architect	6
Student	15
Scholar	4

Table 1: Occupational groups, data from 626 users.

2 Results

2.2 Previously used methods of contraception

There is a noticeable difference in the kind of previous used methods of contraception between the Mexicans and the Europeans.

Whereas the European mainly used oral contraception before (fig. 5a), the majority of Mexicans had used NFP* methods: 16 women did not answer; 10 women had relied on the »Billing« method (21 years in total) and one had used another device (for 2 years). Eleven women had taken the »pill« (17 years) (fig. 5b). Of the 648 European women, a total of 557 (86%) replied to this question. Of these, 478 women (86%) had used oral contraceptives exclusively or in addition to other methods. Only 27 women (4% of BABY-COMP®/LC users) had previously used the NFP method (fig. 5a).

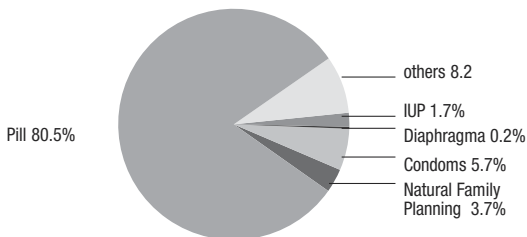


Fig. 5a: Previously used methods of contraception in Germany and Switzerland.
Representation of the proportional period of use in years of 557 women.

*NFP = Natural Family Planning

2.3 Reliability of BABY-COMP®/ LADY-COMP® as a method of contraception

Reliability continues to be the most important criterion in the evaluation of a contraception method.

Already in prior questionnaires about family planning behavior conducted by the Federal Republic of Germany in 1985 and 1989 (Freundl and collaborators, 1991), it was indicated that reliability of a method will become more and more important.

As a result of this study the number of answers stating reliability as the main priority in a method of contraception rose from 89% to 94.1%.

2 Results

2.3.1 Evaluation according to the Pearl Index

The reliability of a method of contraception is usually expressed by the Pearl Index. The formula developed by Pearl is calculated as follows (Pearl, 1933):

$$\frac{\text{Unwanted pregnancies} \times 1200}{\text{User cycles}}$$

This produces an index for the statistical probability of pregnancy occurring in 100 women in one year (1200 months) when using the method in testing.

In the presented study, 39 unplanned pregnancies occurred in 10 601 months. There were 33 unplanned pregnancies in 10 275 months of using contraception among Germans and Swiss. This result also includes those pregnancies which occurred on »red« (=fertile) days (users reliability) as shown on the device as well as the pregnancies which occurred on »green« (=infertile) days.

This means that the following calculation can be made:
 $39 \times 1200 : 10\,601 = 4.4$; if the Mexicans are excluded, we have the following calculation:

$$33 \times 1200 : 10\,275 = 3.8.$$

The Pearl Index for pregnancies occurring on »red« and »green« days in this survey amounts of 3.8 for the Europeans.

2.3.2 Usage safety and method reliability

Unplanned pregnancies can be divided into two categories, depending on their origin:

- An unintended conception can either occur when correctly following the rules of the method, i.e. observing abstinence during the days identified as »fertile« (=red) and »uncertain« (=yellow),
- or when not following the rules by having unprotected coitus during the time identified by the device as being »fertile«.

Correspondingly, we talk of **user reliability**. This takes into account all unintended pregnancies and therefore reflects the everyday efficiency of a method. For the Germans and Swiss in the present study, this corresponds to a Pearl Index of 3.8 in the period under observation (see above calculation.)

This is distinguished from the **method reliability**. Only those pregnancies which occurred when green was displayed are taken into account here. If the women had not entered the information on the questionnaire, telephone enquiries made it possible to ascertain that 6 of the 33 unplanned pregnancies in Europe could be traced to method errors and 27 to user errors.

This means that for **method reliability**, a Pearl Index can be calculated of $6 \times 1200 : 10\ 275 = 0.7$.

2.4 Conception – Planning a child

In our questionnaire, 113 of 648 Europeans said that they had also or exclusively used BABY-COMP® / LADY-COMP® for trying to conceive (table 3). In this context, the device displayed the optimum time to conceive in 106 cases, which was used by 100 couples. Conception took place in 81 cases (81%).

There was a broad distribution (of user time period) and often conception already occurred in the first cycle, whereas for 2 women it only took place after 24 month. The mean user time period to achieve conception was 4.5 months.

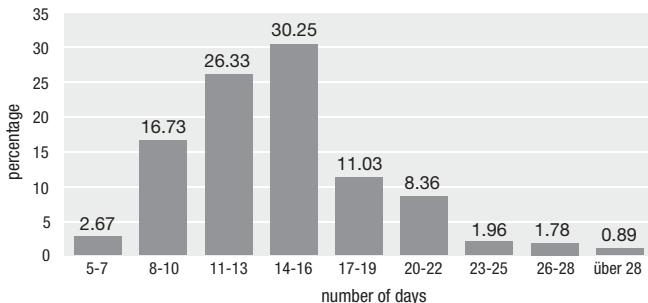
Used for conception planning	113
used conception optimum	100
number of pregnancies	81
%-proportion of pregnancies	81% (71%)

Table 3: Use of the device for conception planning.

Only BABY-COMP® provides a sex prognosis. Of the 81 pregnancies, BABY-COMP®'s sex prognosis was used in 19 cases. The sex prognosis was accurate in 10 cases; in the other 9 cases, the device either showed an equally high probability for »boy/girl« or the prognosis was inaccurate.

2.5 Length of the fertile phase

The average length of the fertile phase indicated by BABY-COMP®/ LADY-COMP® was 14.3 ± 4.6 days. For more than 50% of users, the length of the fertile phase lay between 11 and 16 days (fig. 9). The mean cycle length (data from 419 women) in our study was 29.2 ± 5.4 days.



3 Satisfaction

3.1 General

The number of potential advocates of this technology was remarkable:

90% of users of BABY-COMP® / LADY-COMP® would recommend this device to others; many of them also expressed their satisfaction at finally finding a reliable method of contraception without side-effects (fig. 12.)

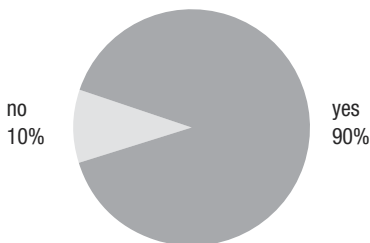


Fig. 12: Evaluation of the computer by the users (»would you recommend BABY-COMP® / LADY-COMP® to others?«) (n = 686, of which 618 »yes« responses, and 68 »no« responses).

3.2 Attitude of the partner

Since the success of the method (behavior) is decisively influenced by the involvement of both partners, the questionnaire included questions concerning the partner's attitude.

Users were asked about their partners' attitudes when first introducing the device BABY-COMP® / LADY-COMP® and »now«. In the course of the period of use, there were a few partners whose attitudes were described as deteriorating from uncertain towards negative.

There were only limited differences between the Europeans and the Mexicans concerning this point. The majority of partners were on the whole »positive«. However this trend generally increased among the Europeans and declined among Mexicans (fig. 13).

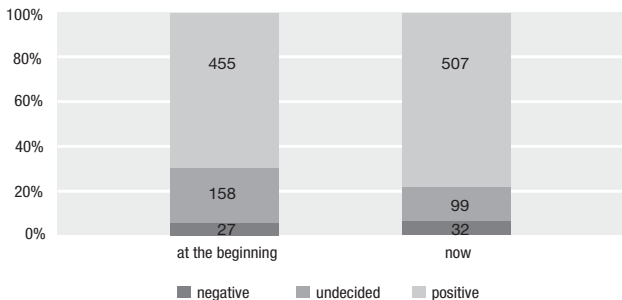


Fig. 13: Partners attitude to BABY-COMP® / LADY-COMP® at the beginning and at the present time; responses from 640 Europeans.

4 Questionnaire

Scientific Survey in connection with a Dissertation at the University of Dusseldorf

A) A) How did you hear about **BABY-COMP®/ LADY-COMP® (= BC/LC)?**

- newspaper article doctor
 advertisement pharmacy
 friend

Approximate date of purchase

Have you used BC/LC right up to today? Yes No

If no: I used it formonths
Why do you no longer use it?

Please still return the questionnaire.

B.1) How many times did you forget to take your temperature during one cycle? about.....days

What is your partners opinion of BC/LC?

	positive	undecided	negative
at the beginning	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
now	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Did you use other methods of contraception prior to BC/LC?
Which?

For how long?years

Do you have children? Yes No

If yes how many?

On how many days of your last cycle did BC/LC show
red? yellow? green?
..... /..... /.....

Did you experience an unwanted pregnancy during the time of use?
 Yes No

Did you have problems with too many red days?
 Yes No

B.2) Did you use BC/LC for conception planning?

Yes No
If no, go to B.3

How long have you been trying to get pregnant?
since.....

Did BC/LC show you the best days for conception? Yes No

Did you use this information?
 Yes No

Did you get pregnant?
 Yes No
If yes, how long had you been trying?
.....years

4 Questionnaire

If no, do you know any reason why you did not get pregnant?

Did BC/LC indicate the pregnancy?
 Yes No

Did BC/LC give you an accurate sex prognosis?
 Yes No

If yes, was it a
 boy girl

When was the expected date of delivery according to BC/LC?
Date.....

Which date did the obstetrician calculate?
Date.....

When was the baby born?
Date.....

Was the birth induced?
 Yes No

Did you have a miscarriage?
 Yes No

If yes, did BC/LC indicate this?
 Yes No

Did BC/LC indicate a pregnancy outside the womb?
 Yes No

B.3) General

Did you have problems taking temperature readings?
 Yes No

other problems

Would you recommend BC/LC to others?
 Yes No

Would you please give your age
19.....
your weight? kg.....
your height? cm.....

What is your occupation/job?
If your address has changed, please complete the following.

first name, name

number/street

post code/town

I would like to receive a summary of the results.
 Yes

Please send the questionnaire to:

If you have any other questions, please give us a call.
Monday-Friday 8.30 -16.30

Many Thanks For Your Cooperation!



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