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Original Article

Development of a Permanent Device for Fertility Period Detection by Basal Body Temperature and Analysis of the Cervical Mucus Potential of Hydrogen

Abstract

Background: Sometimes, women find it difficult to conceive a baby and others use contraceptives that often have side effects. Researchers have already established the importance of measuring basal body temperature (BBT) and the potential of hydrogen (pH). **Method:** We have designed and realized a device that allows the simultaneous measurement of the BBT and the pH. We used an Arduino Uno board, a pH sensor, and a temperature sensor. The device communicates with a smartphone, can be integrated into all e-health platforms, and can be used at home. We validated our ovulation detector by a measurement campaign on a group of twenty women. If the pH is >7 and at the same time, the BBT is minimum and <36.5°C, the women is in ovulation phase. If the pH is ≤7 and in the same time, the BBT is between 36.5°C and 37°C, the women are in preovulation or follicular phase. If the pH is ≤7 and in the same time, the BBT is >36.5°C, the women are in postovulation or luteal phase. **Results:** We tested the contraceptive aspect of our ovulometer on a set of seven women. We also tested the help of conceiving babies by having intercourse during the ovulation period fixed by our ovulation detector. The results are satisfactory. **Conclusions:** In the final version of our device, we displayed just in "fertility period" if the pH is ≥7 and the BBT is <36.5°C else we displayed in "nonfertility period."

Keywords: *Cervical mucus, contraception, ovulation, pH sensor, temperature sensor*

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Introduction

Some women find it difficult to conceive a baby despite months of sexual intercourse and others use contraceptive methods to prevent unwanted pregnancies. The objective was the development of a new method that helps women to conceive a baby or to prevent pregnancies. This method was based on the precise determination of the ovulation period.

M. Owen described the physiological signs of ovulation.[1] There are several methods to determine the ovulation period, some of which are effective and others much less. Su *et al*. presented a review of currently available methods for the detection of ovulation.[2-6] Some ovulation detection devices have been developed and commercialized based on these methods.[2]

Among these methods, one can distinguish the use of the ovulation test. This method involves the use of urinary luteinizing hormone (LH) tests to predict ovulation using a urine sample. Ovulation occurs after 24–38 h of the LH peak, which makes it easier to spot the day of fertility. The peak corresponds to the appearance of two small black bars that indicate that the egg is ready to be ejected. It is advisable to balance the water consumption and use the test at the same time of the day throughout the cycle to obtain a more accurate estimation.[7-9]

The second method is the monitoring of basal body temperature (BBT). It consists of establishing a measurement curve of body temperature everyday before waking up after at least 5 h of sleep taken over several days and menstrual cycles. The measured values must be taken with the same processes (use the same thermometer, the same angle, and at the same time) and will then be recorded on a sheet ready to fill. Ovulation occurs when the curve data show the lowest temperature of the

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follicular period, just before the thermal increase. With data collected over several months, it will be easier to estimate the ovulation period during the cycles. It should be noted, however, the days when the temperature would have been influenced by other events such as illness, medication, or a sleepless night.[10,11]

The third most used method is the calculation of menstrual cycles. This method involves using a calendar to count and date the menstrual cycles to determine the ovulation period. This technique is not precise, especially for an irregular cycle, but it allows determining a range of days where the period of fertility is.[12-14]

We can also enumerate mobile applications that allow women to follow their menstrual cycle with their smartphones. We simply record the start date of the last rule and the normal cycle time. It should be noted that this type of tool is recommended if the cycle is regular because the dates provided are approximate and are valid only when the menstrual cycle is correct. We enter the date of the first day of last period and the average cycle length. Then, we obtain the ovulation window and the next period date.[15-17]

Contraceptive methods are based primarily on the use of pills, intrauterine device, and the contraceptive patch. Indeed, the pill is the most used method that replaces the natural sexual cycle of women by an artificial cycle making the ovaries unable to release eggs.[18,19]

The objective is the precise determination of the fertility period. It could help according to our wishes to contraception or to the conception of a baby. To do this, we designed a device based on the measurement of the potential of hydrogen (pH) of the cervical mucus and the BBT.

Materials and Method

To achieve this goal, which will allow women who want to conceive a baby to choose the right time and avoiding sexual intercourse during the period of ovulation, we get the best contraceptive method without complications; we designed and realized a system allowing a precise determination of the ovulation period. The system is based on the measurement of two parameters, the first is the pH of the cervical mucus and the second is the BBT.

Methods

The menstrual cycle consists mainly of three phases: the preovulatory phase, the ovulatory phase, and the postovulatory phase. Each phase is characterized by specific events related to the secretion of ovarian hormones that influence temperature and cervical mucus.[1,20] The average duration of a menstrual cycle is 28 days with most cycle lengths between 25 and 30 days.[21] A short as 21 days or long as 35 days are also normal. The cervical mucus is a viscous, transparent fluid secreted by the cells of the cervix under the action of estrogen. Indeed, the quality and quantity of vaginal discharge, as well as body temperature, can tell us about the variation in factors related to the rules, the period of ovulation, and pregnancy.[22,23] The preovulatory phase (also known as the follicular phase) is a duration variable phase between 10 and 17 days and begins with the bleeding which comes from the destruction of the uterine lining and which lasts generally between 3 and 7 days; it is a totally infertile period.

After the menses and during the days preceding ovulation, the follicle-stimulating hormone stimulates follicular growth that causes estrogen secretion and endometrial proliferation to prepare for implantation of the egg.[21] The cervical mucus is acidic, scanty, and has a very tight mesh, which prevents the sperm from crossing the uterus.[24] This acidic vaginal environment is toxic to the sperm. The closer the day of ovulation, the more the estrogen secretion increases and the mucus increases in quantity and fluidity.

For the temperature, the release of progesterone hormone by the follicles is low which explains the oscillation of the body temperature value between 36.4°C and 36.7°C.

The ovulatory phase, during a regular cycle, ovulation usually occurs about the 14th day after menstruation with the influx of estrogen, which stimulates the secretion of LH, which causes the follicle to rupture, resulting in the release of the ovum.[8]

A few days before the ovulation and until day "d," the cervical mucus becomes abundant, fluid, and basic; these variations favor the passage of the spermatozoa from the uterus toward the tubes and ensure the protection of the sperm.[22]

Just before ovulation, the temperature drops to the lowest point of the cycle at about 36.4°C.[25]

During the postovulatory phase (also known as the luteal phase), the empty follicle turns into a corpus luteum, luteal cells produce estrogen, and a large amount of progesterone closes the cervix to prevent sperm and bacteria from crossing it. In addition, progesterone maintains body temperature above 37°C and dried vaginal secretions from where its pH is again acidic.

In this phase, due to the increased secretion of progesterone by the corpus luteum, the temperature often rises above 37°C.[11] At the end of the cycle, if no fertilization, the endometrium will disintegrate and be rejected by the vaginal orifice and the temperature will return to its normal level just before the bleeding. It should be noted that the fertility period begins 1 day before ovulation and that the egg lives only 12–24 h later, and sperm lifespan in female body is between 3 and 5 days.

Table 1 summarizes the changes in pH and temperature (BBT) during the menstrual cycle.

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As stated above, the precise determination of the pH of the cervical mucus associated with the measurement of temperature can tell us about the phase of the menstrual cycle.

The purpose of the designed system was to accurately measure pH and temperature and, depending on the values, tell the user whether she is ovulating.

Materials

We opted for the design of a device that can be used at home, precise, low cost, connected, and easy to use. For that, we chose to work with an Arduino card, which allows us to improve the performance of our device by simple modifications of the code. To measure the pH of the cervical mucus and the BBT, we used two sensors.

A pH probe connected to the Arduino Uno board via an SEN0161 interface [Figure 1]. The pH module is connected to the A0 analog input of the Arduino Uno. An analog/digital converter that converts an analog voltage into a sequence of bits "0" and "1" drives this input. This binary sequence is translated by the map into a number varying from 0 to 1023. Then, the use of the "map" function in the Arduino code is essentially to adapt the measurement interval of the conversion (0 … 1023) and the measuring interval of the pH meter (0 … 0.14).

The second sensor was used to measure the BBT. It can be used with Arduino [Figure 2].

The general synoptic of the ovulation detector is given by Figure 3. The designed system consists essentially of a pH sensor and a BBT sensor connected to an Arduino Uno board. The processing is done at the Arduino Uno board and the result is displayed by the LCD display.

The result can be sent to a smartphone via the Bluetooth module HC-05 which allows wireless communication with the Arduino module through a "master-slave" connection method. The Arduino Uno developed program flowchart is given in Figure 4.

By testing the designed device and whose program implemented in the Arduino Uno board is described by the flowchart of Figure 4, we obtained the following result [Figure 5]. The system designed (also called ovulation detector or ovulometer) by measuring pH and BBT could accurately determine the ovulation period.

Knowing this period, the woman who wants to be pregnant must have an intercourse. Women do not want to be pregnant, just abstain during this period.

Results

To verify the proper functioning of the designed system, we first compared the determination of the pH and the temperature to reference devices. Table 2 presents the measured values of pH buffers for calibration by the designed device and by the PeakTech P 5310,

Table 1: Potential of hydrogen and temperature values during the three phases

	Follicular phase	Ovulatory phase	Luteal phase
pH	≤7	>7	≤7
BBT (°C)	36.5≤ T ≤37	36.2≤ T ≤36.4	36.5≤ T

BBT – Basal body temperature; pH – Potential of hydrogen

Table 2: Potential of hydrogen measurement by the designed device and by the PeakTech P 5310, potential of hydrogen -Meter

pH buffers	pH, reference device	pH, designed device
2	2.06	2.21
4	4.05	4.13
5	5.03	4.97
6.865	6.86	6.81
7	7.05	7.07
8	7.97	8.07
10	9.96	9.92

pH – Potential of hydrogen

Figure 1: Potential of hydrogen sensor (Arduino compatible)

Figure 2: Body temperature sensor for e-health platform

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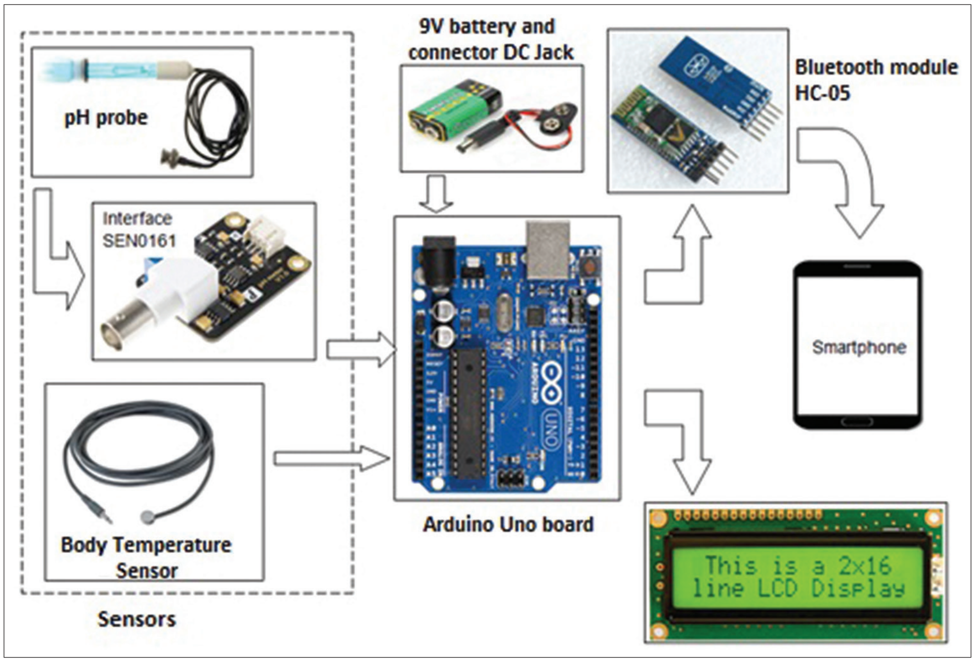

Figure 3: The general synoptic of the ovulation detector

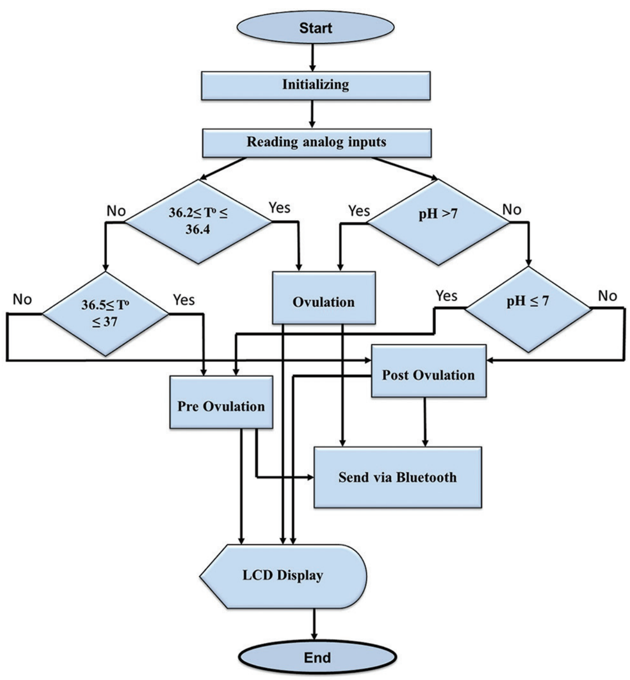

Figure 4: Arduino uno program flowchart

PH-Meter.[26] The percentile error was 2.55%. For each pH measurement, we repeated the measurements five times. For the first measurement, the mean was 2.21; the standard deviation was 0.16 and the 95% confidence interval, 2.21 ± 0.157.

Table 3 presents measurement of different temperature values by the designed device and by the PeakTech 5135 digital thermometer.[27] The percentile error was 0.99%.

Table 3: Temperature measurement by the designed device and by the PeakTech 5135

T°C	T°, reference device	T°, designed device
25.8	25.8	25.3
26.9	26.9	26.45
30.15	30.15	30.01
37.03	37.03	37.17
37.5	37.5	37.69

Then, we measured during a menstrual cycle the pH and BBT of three different women. Figures 6 and 7 show the change in pH and temperature of one of the three women.

A series of pH and BBT measurements were taken during a menstrual cycle, at the same time at the same time. This is a normal cycle that lasted 28 days.

The beginning of the cycle was April 12, which was the 1st day of bleeding. No action was, therefore, taken during the first 5 days of the cycle. April 17 was the 6th day of the cycle; the pH was 4 and then gradually increases to 6 on April 22. It should be noted that this period corresponds to the preovulatory phase characterized by the acidic pH of the cervical mucus. April 23 was the 14th day of the cycle, the pH was 7, and the mucus was not yet basic.

April 24 was the 15th day of the cycle, which coincides with a pH of 8; it is noted that this period corresponds to the ovulation phase which is characterized by a basic pH of vaginal secretions and lasts only 24 h.

April 25 was the 16th day of the cycle; the pH was 7 and then gradually decreases to 4; it is noted that this period corresponds to the postovulatory phase characterized by

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Figure 5: The designed device display that the woman is in preovulation phase with a potential of hydrogen = 7 and a Basal Body Temperature (BBT) = 36.66°C

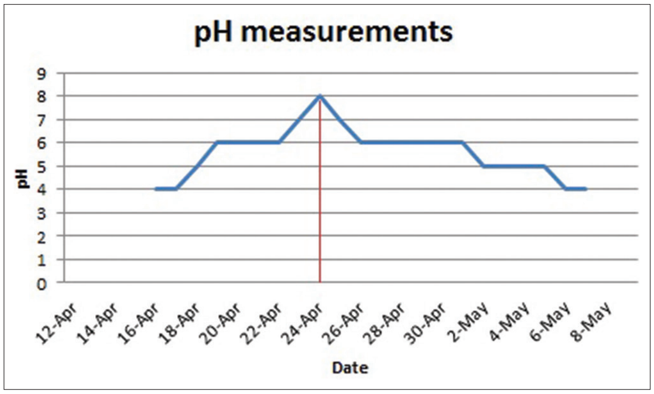

Figure 6: Potential of hydrogen measurement of cervical mucus during a menstrual cycle

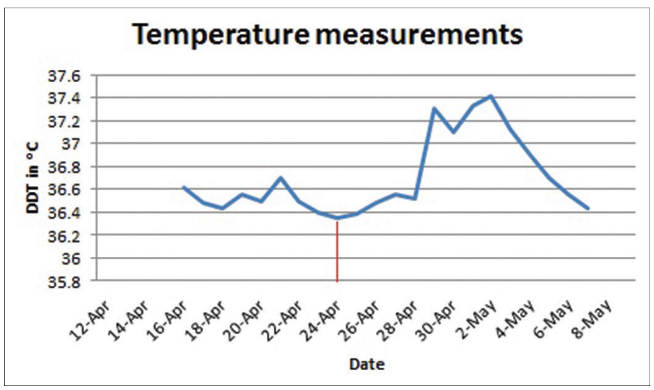

Figure 7: Temperature measurements during a menstrual cycle

acidic pH of the cervical mucosa. During the cycle and although the pH of the cervical mucus was only basic for a single day, the chances of fertilization were high for 48 h.

We conducted a second campaign of pH and BBT measurements on a group of twenty women to find if they are ovulating or not. All the women were voluntary and signed a consent document, which specified the nature of the measures to be taken. In addition, the measures are noninvasive, nondangerous, and has no effect on women volunteers and between each measurement, the designed system is sterilized. In Tunisia, when we had carried out the measurements, there was not yet an ethics committee, but the study followed the principles of the Declaration of Helsinki.

Table 4 presents the results. To be able to confirm or not the ovulation, we used the Easy@Home ovulation test.[28] All the results presented in Table 4 are identical except for the thirteenth subject; the designed system indicated ovulation period and the Easy@Home ovulation test predicts not ovulation.

The women interviewed did not want to know if they are in pre- or postovulation, but just to know if they are in ovulation or not. It means that they want to know the appropriate time for fertilization for those who want to have a baby and the period that does not present any risk of getting pregnant for those who do not want to have babies.

Among this group, ten women were married, seven of them did not want to have children. We asked them to avoid intercourses during the ovulation period (determined by our ovulometer). For 6 months, none of them became pregnant.

The three women desired to have a baby, we asked them to have intercourses in the ovulation day determined by our ovulometer. After 6 months, two of them became pregnant.

For women who became pregnant, we tried to track pH and temperature during the first few days. We noticed just before the menses that the temperature remained around 37°C and did not decrease.

We will work on this to make our system capable of detecting pregnancy.

Figure 8 presents the period of fertility and the period of nonfertility that is why we changed the flowchart of our program, as shown in Figure 9.

In conclusion, the ovulation occurs only if at the same time, the pH is >7 and the BBT is minimum and <36.5°C. If the pH is ≤7 and at the same time, the BBT is between 36.57°C and 37°C, the women are in preovulation or follicular phase. If the pH is ≤7 and at the same time the BBT is >36.5°C, the women are in postovulation or luteal phase.

Discussion

The designed system uses the pH of the cervical mucus and the BBT to determine the fertility period with precision. All published papers had use urinary LH tests to predict ovulation using a urine sample.[7-9]

Other authors have highlighted the importance of the basal temperature to differentiate the fertility and nonfertility periods.[29]

In this article, we have demonstrated the relevance of pH measurements of cervical mucus. No published article has studied this parameter.

The proposed method and device are original and will be the subject of a patent application.

Conclusions

We demonstrated the importance of using the pH and BBT measurements to predict the different phases of the menstrual cycle. We designed a new ovulation detector device that can be used for the conception of babies by

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Table 4: Potential of hydrogen and basal body temperature measurements and decision

Subject N°	Age	Status	Weight (kg)	Height (m)	Day of the cycle	T °C	pH	Ovulation (yes/no)
1	20	Married	75	1.71	7th	36.8	6	No
					13th	36.5	8	Yes
					18th	37.2	5	No
					26th	37.4	5	No
2	40	Married	70	1.6	End of cycle	37	6	No
					15th	36.5	9	Yes
3	24	Married	62	1.68	8th	36.7	6	No
					10th	36.7	6	No
					14th-20 H	36.5	8	Yes
					15th-10 H	36.4	9	Yes
4	39	Married	77	1.69	7th	36.9	5	No
					13th	36.6	7	No
					14th	36.4	9	Yes
					15th	36.5	8	Yes
					16th	36.9	7	No
					20th	37.1	6	No
5	26	Married	54	1.71	6th	37	5	No
6	22	Single	69	1.69	7th	36.8	5	No
7	27	Single	77	1.68	8th	36.8	5	No
8	20	Single	73	1.64	9th	36.8	6	No
9	22	Single	63	1.65	10th	36.7	5	No
10	36	Married	73	1.64	11th	36.9	6	No
11	23	Single	59	1.69	12th	36.7	6	No
12	42	Married	81	1.66	13th	36.6	7	No
13	40	Married	87	1.73	14th	36.4	8	Yes
14	19	Single	55	1.67	16th	37	7	No
15	25	Single	59	1.73	17th	37.3	6	No
16	35	Married	64	1.72	20th	37	5	No
17	20	Single	59	1.70	End of cycle	37	6	No
18	22	Single	65	1.59	End of cycle	37.2	5	No
19	18	Single	55	1.67	End of cycle	37	5	No
20	21	Married	70	1.66	End of cycle	37.2	4	No

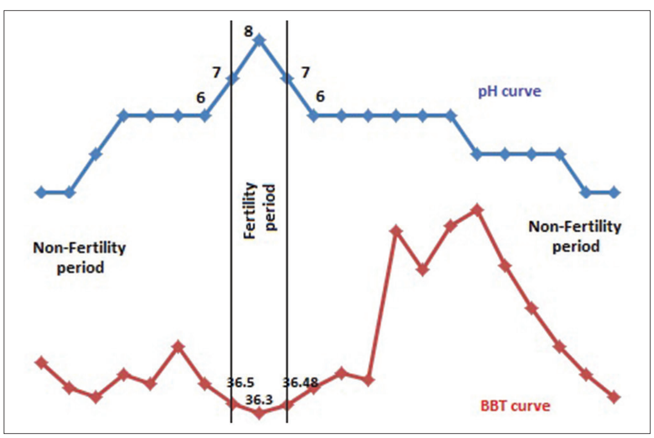

Figure 8: Periods of fertility and nonfertility

precisely determining the ovulation period or as a means of contraception, specifying the period during which it is necessary to refrain from having intercourses. The designed ovulometer is based on the measurement of the pH of the cervical mucus and the BBT.

If the mucus is acidic and the BBT is >36.4°C, the woman is in the follicular or luteal phase or nonfertility period, otherwise, she is in the ovulation period or fertility period.

We performed a measure campaign on a set of twenty women. The results are satisfactory. We tested successfully the contraceptive aspect of our ovulometer on a set of seven women. We also tested successfully the help of conceiving babies by having intercourse during the ovulation period fixed by our ovulation detector. The procedure of the designed device is different than the commercial devices. Most commercial ovulation test devices use test strips to analyze urine LH. We must use a new strip for each test. With the proposed device, the same pH sensor is used each time to analyze the acidity of the cervical mucus. In addition, the system is lower cost, connected, easy to use, and may allow the determination of the heart rate in future.

Several improvements are possible to improve the sensitivity of the designed system by performing a

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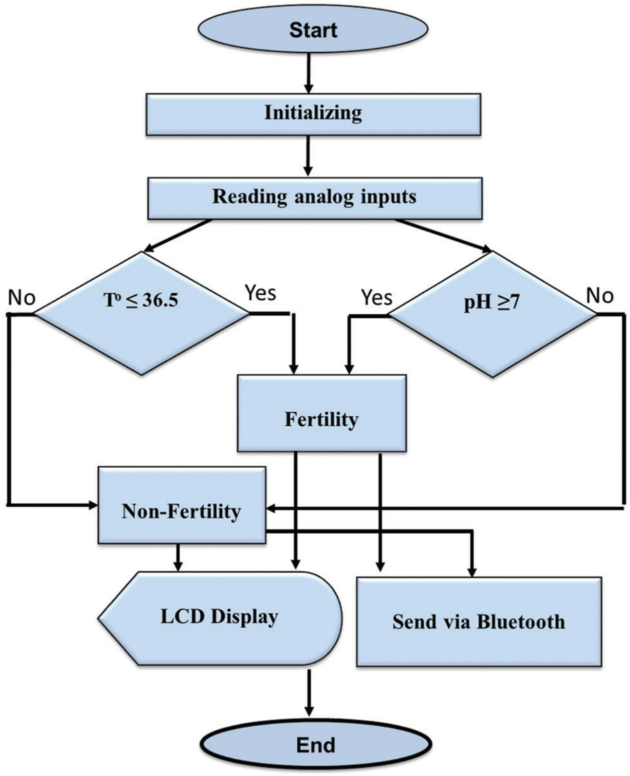

Figure 9: The final arduino uno program flowchart

large validation campaign and making it able to detect pregnancy.

This will allow us to have a device that can have three roles, contraception, the ovulation detector, and pregnancy detector.

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None.

Conflicts of interest

There are no conflicts of interest.

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BIOGRAPHIES

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