Design Concepts and Operation Principles for Smart Intra-Vaginal Health Monitoring Devices

Lewandowski, J. , Chao, K-M. and Nizański, W.

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Jacek Lewandowski, Kuo-Ming Chao
School of Computing, Electronics and Mathematics
Coventry University
Coventry, UK
j.lewandowski@coventry.ac.uk, k.chao@coventry.ac.uk

Wojciech Niżański
Dep. of Reproduction and Clinic of Farm Animals
Wroclaw University of Environmental and Life Sciences
Wroclaw, Poland
wojciech.nizanski@up.wroc.pl

***Abstract*— The proposed work is the conception of a novel intra-body sensor device capable of measuring and gathering long-term intra-vaginal pH and temperature. At its early stage this project focuses on the analysis of different design concepts and operation principles of such intra vaginal sensor device. Traditional methods of intra-vaginal pH sampling, which rely on analysis of vaginal secretions or discharge from lateral vaginal walls, are difficult in long-term and often fraught with the potential for errors. Therefore this paper focuses on the analysis of such sensor's shape, form, size and fabric in order to enable precise, continuous acquisition of females' and animals' intra-vaginal pH and temperature at the right place inside the vagina. The aim is to set such operation principles, which will enable convenient collection and analysis of continuous vaginal pH and temperature samples for the purpose of further study. The objective is to achieve at least as accurate results as with the discrete analysis of clinically-obtained intra-vaginal specimens, if not better. The data obtained with such sensors could enable a development of insemination prediction and gynaecological disorders detection models, which deployed to, for example smartphone devices, will help to attain high conception rate for animals and eventually improve the control of the vaginal health for women.**

Keywords-component; Wireless Body Sensor; health monitoring; ph; temperature; intra-body sensor

I. INTRODUCTION

With the advancement of e-health, an increasing number of biomedical sensors are being implanted and worn by humans for the monitoring, diagnosis, and treatment of diseases. Nowadays, body sensor systems are very helpful medical diagnosis methods. Most common measurements, are related to physiological functions or indices such as: ECG, respiration, blood pressure or temperature, amongst others. They present a potential to provide critical information that could enable the assessment of the long-term health status of an individual, and early diagnose of any unsought health status changes.

Body sensors could be classified generally in two groups according to their placement: i) body sensors that are used outside of the human body, most of which operate in contact with skin, and ii) intra-body sensors, that are placed inside the human body. The second group can be further split into: iia) implantable sensors placed in closed body cavities such as the cranial, vertebral, thoracic or abdomino-pelvic cavities, and iib) intra-body sensors placed in open body cavities such as nose, mouth, ear, throat, vagina, or rectum. While implantable sensors normally require a surgery to place sensors in their desired positions, intra-body sensors can be non-invasively placed by patient his/herself.

Continuous, wireless, in-vivo pH and temperature monitoring device, which design concept is proposed in this paper, will help us better understand vaginal pH and temperature variations, what combined with the accurate and timely operation principles proposed, have a great potential in veterinary to improve early detection and notification of heat in animals as well as in human gynaecology to support illness prevention and early detection, enabling women's self-management of wellness.

II. BACKGROUND

The normal vaginal ecosystem in mature women is maintained by Lactobacilli species, with a resulting pH < 4.7 which is recognized as a level limiting overgrowth of opportunistic microbes [1]. It prevents potentially serious gynecological and obstetrical complications arising from an abnormal vaginal ecosystem. A slightly acidic vagina is a perfect environment for the types of good bacteria that help keep the vagina clean and healthy, while the most harmful bacteria have a hard time surviving in an acidic environment. Keeping those harmful bacteria at bay is not only important for general hygiene and comfort, but also to help avoid infection and diseases. pH level above 4.7 can make women more susceptible to vaginitis, or inflammation of the vaginal tissue, which can be caused by infections like yeast and bacterial vaginosis (the most common cause of abnormal vaginal discharge) or irritation from feminine products [2] Moreover, elevated pH favors Sexually Transmitted Infections (STI) such as trichomoniasis [3], HIV infection [4], Chlamydia trachomatis and mycoplasma [5] or HPV infection [6] amongst others. In extreme cases, bacterial vaginosis may cause infertility. Moreover, the pregnant women with the infections, can lead to transmission of infection from mother to new-born babies.

Furthermore, self-sampling of intra-vaginal pH is often fraught with the potential for errors. Clinicians usually obtain vaginal secretions or discharge in a sterile environment from lateral vaginal walls with a small cotton-tip applicator. This is then transferred to a strip of pH paper and compared with a standard colorimetric reference chart to estimate the actual pH. However, pH within the vagina is not uniform and depends on location, becoming less acidic towards the introitus. In addition, false elevations of pH may be encountered when semen, mucus, or blood is inadvertently sampled [7]. Because self-sampling of vaginal secretions may vary in technique (depth, duration, and position) among women, pH results may also vary accordingly.

Given the above, we can clearly demonstrate the value of continuous monitoring the pH of the vaginal environment in the prevention of numerous infections, especially sexually transmitted diseases. Further study of this problem with help of advanced electronic intra-body devices, computer data mining techniques and simulations can help create effective mechanisms for detecting disturbance of the normal vaginal pH level.

In turn in animals, for example cattle, vaginal pH and temperature are varying with different phases of estrous cycles and could be good indicators of animal in estrus, what is crucial in proper heat detection to achieve appropriate timing of insemination. Each missed heat is equivalent to 21 days loss in production [8], what is the biggest restriction in attaining high conception rate in dairy herd. The ultimate goal of heat detection is to predict actual time of ovulation [9] As heat detection is labor intensive and time consuming method, its success is crucial for dairy farms. As estimated by Senger [10] the U.S. dairy industry only, loses more than $300 million annually due to failure and/or misdiagnosis of estrus.

In light of this findings, continuous analysis of variations in vaginal pH in dairy cattle over the monoestrous cycles period have, to the best of our knowledge, not been reported. Further study of this problem enabled by this prime research project, will provide better understanding of vaginal pH and temperature variations. Combined with the accurate and timely monitoring proposed in this project, could have a great potential in veterinary to improve early detection and early notification of heat and vaginal pathological conditions.

A. Related Works

Over the last few years many researchers have been working on development of medical sensors for female physiological parameters monitoring. However, so far, all these projects were aimed at intra-vaginal temperature monitoring only. Using various types of in-vivo temperature probes, researchers have been striving to find the relationship between temperature and certain female conditions, such as ovulation period.

One of the first projects, aimed at female temperature monitoring and analysis, was DuoFertility Project [11]. It was developed as a trail commercial system for detection and calculation of both ovulation and fertile periods. It measures female’s body skin temperature every 10 minutes using a sensor reader located under the arm. However, such indirect vaginal temperature estimator could be influenced by environmental conditions, leading to poor accuracy and wrong results for this type of studies. Despite several limitations, recent research on infertile women with regular cycles [12] shows, that DuoFertility monitor appears to accurately identify ovulatory cycles and the day of ovulation.

The only commercial device for intra-vaginal monitoring identified in the literature review, is called PriyaRing [13]. It is a self-inserted flexible vaginal ring, that continuously monitors core body temperature, and passively communicates it to a smartphone application. The multi-site study [14], which compared this device with other commonly used methods for ovulation prediction, confirmed that it can accurately measure continuous core temperature and circadian rhythm and provide a novel, safe, effortless and more accurate method of ovulation prediction.

As literature shows, the intra-vaginal temperature monitoring is not limited to humans and has been investigated for various household animal species, such as sheep or diary heard. Such monitoring devices often base on the range of commercially available intravaginal drug delivery technologies used in farmed animals. An example of such temperature monitoring device, consisting of a blank controlled internal drug release (CIDR) device that holds an indwelling vaginal temperature probe logger, was proposed by Burdick et al.[15]. It was used for the measurement of vaginal temperature in dairy cattle, without the potential biases associated with the stress response produced as a reaction to the handling by and (or) presence of humans. Their prototype vaginal probe, costing approximately US $325 per unit, decreased farm labor, increased the precision and decreased the timing of vaginal temperature checks to 1 min intervals, providing researchers with an inexpensive and more accurate tool to study physiological responses in female cattle.

Unlike the existing projects, this research aims at extending the set of physiological parameters being monitored by intra-vaginal pH measurement, which combined with temperature provides a very reasonable assessment of vaginal health and/or ovulation period for both animals and humans. In the prototyping stage of this project we chose cattle’s vagina, which pH behaves very similar to human female’s vagina, but at the same time cattle’s vagina is bigger in dimension, therefore easier and less expensive for experimentations.

III. Design Concepts

In this paper we discuss design concepts of intra-vaginal pH and temperature sensor device with applications to both human and animal (cattle) vaginal pH monitoring. The intra-vaginal probe for women, should enable them to conveniently self-collect and analyze vaginal pH and temperature samples in household environment without the need to attend gynaecologist for rather uncomfortable and unpleasant examination. The objective is to achieve at least as accurate pH and temperature sampling results as with analysis of clinically-obtained intra-vaginal specimens, if not better.

A. System Requirements

In order to get accurate readings, both sensors should be placed inside a specialized enclosure at the correct position inside the vagina. It should be anatomically comfortable and its application should be trivial for a women as well as farm labor. Moreover the proposed system should consist of a complimentary smartphone or smartwatch application, which will pre-process, analyze, transmit and present measurements and results of the analyses to the user. To implement this concept a non-intrusive and chemically neutral sensors and sensors enclosure materials should be used to ensure the health and safety of this device. Immediate signal pre-processing on the mobile device and further analyses in cloud should help in early detection, diagnoses and treatment of various vaginal health conditions. Therefore analysis should focus on:

- types of medical-grade pH and temperature sensors,
- shape and size of sensor housing,
- types of biocompatible materials for sensor housing.
- wireless sensor probe design and system architecture,

B. Types of suitable pH and temperature sensors

Requirements for the in vivo sensors are: 1) materials biocompatibility, 2) high measurement precision, 3) a response time of an order of less than seconds, and 4)the possibility of continuous 24-h monitoring. To avoid infection and spread of diseases, in vivo monitoring devices should be personal and either single-use/disposable or sterilisable, what puts extra restrictions on the price and stress out their temperature and chemical resistance.

Medical grade temperature sensors can take a variety of forms to help fit particular application. Typically, NTC thermistors are the ideal solution for monitoring temperature at 37°C (normal human body temperature). NTC thermistors can provide unparalleled accuracy and sensitivity in the body temperature range. Additionally, because of their low cost at high volumes, thermistors are the perfect temperature sensor choices for disposable medical applications.

While in-vivo temperature monitoring can use fairly typical thermistors, there are various potential methods and materials to be used for in-vivo measurement of pH levels. This include optical fibers, pH-sensitive polymers, potentiometric pH sensors, near infrared spectroscopy, nuclear magnetic resonance, and fluorescent pH indicators.

According to the Korostynska's et al [16] comprehensive review of pH sensors, the most promising option for in-vivo pH monitoring is a potentiometric pH sensor. Potentiometric pH sensor has two electrodes: one of them is fabricated from an inert metal and is used as a reference electrode (usually made from Ag/AgCl), while the other electrode has a pH-sensitive layer deposited onto it. As a result, a potential difference is generated between the two electrodes (open circuit potential), and its magnitude is proportional to the pH of the solution.

Among this type of sensors are ion sensitive field effect transistors (ISFET). ISFET is based on the surface adsorption of changes from the solution under test in the solid-electrolyte interface that is part of the gate of the ISFET. However, typical ISFET sensors for continuous pH determination, have a major drawback for in-vivo applications, due to brittle silicon substrate. Moreover, widely used glass membranes for such pH reference electrodes suffer from a number of serious disadvantages for biomedicine, such as slow response times, high impedance, mechanical fragility, requirement for frequent recalibration, and vulnerability to membrane fouling with consequent loss of accuracy and precision.

ISFETs biocompatibility can be improved with CMOS technology, as demonstrated by the SmartPill and BRAVO ingestible pills [17] for gastrointestinal tract evaluation. CMOS-compatible ISFET sensors are based on the surface adsorption of charges from the solution under test in the gate oxide-electrolyte interface, which modulates sensor's threshold voltage. CMOS ISFETs can replace the standard ion-sensitive electrodes and offer small size, robustness, and potentially small cost.

C. Sensor housing design

Considering working environment of the proposed sensor, it has to respect some anatomic limitations of the monitored object. It should have right size, be comfortable, easy to place and remain in the right position inside the vagina. For this purpose we investigate applicability of various types of both human and dairy cattle's intra-vaginal inserts, to house both temperature and pH sensors along with electronics, batteries and RF transmitters.

1) Female's ph sensor housing

There is a wide range of commercially available intravaginal inserts in different shapes, used for various gynecological purposes, Inserts, illustrated in Figure 1, be considered for pH sensor housing are: a) tampon used for period control; b) 'T'-shaped Intra Uterine Device (IUD), and c) vaginal ring, both used for pregnancy control.

a)

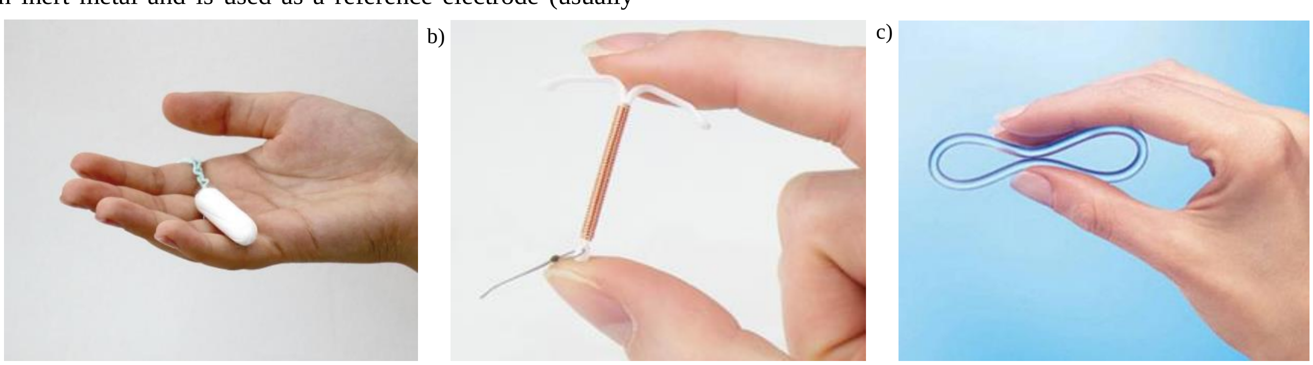

Fig. 1. Various female's intra-vaginal inserts types: a) tampon-like; b) 'T'-shaped IUD-like; c) vaginal ring.

The use of a shape similar to a trivial tampon seems to be the first and obvious choice. Tampons are inserted completely inside the vaginal canal and rests just below the cervix, where is the right place for pH measurement. Tampons are well known by women, easy to use, anatomically perfect, and have the size to accommodate all required sensors' components. Moreover, it has the string, hanging out of the body, which is used to pull it out. It is a perfect element to accommodate transceiver's antenna and make it external to the body, which will eliminate the risk associated with excessive exposure to radio frequencies.

However, typical tampon poses certain limitations of which the most significant one is its recommended length of continuous use, which is limited to 8 hours, after which the tampon should be removed in order to eliminate the risk of Toxic Shock Syndrome (TSS). TSS can occur when certain strains of bacteria are allowed to multiply through the contact with mucus membranes or tears in tissue. Although it is very rare, tampons can result in TSS as they allow bacterial growth within the vagina and by drying-out mucus membranes cause damage in vaginal walls. Moreover, pH sensors placed inside the tampon-like enclosure cannot be used during sexual intercourse or other vaginal sexual activity, when pH measurements would be the most desired in order to detect and counteract STI transmission. Aforementioned problems do not refer to vaginal rings or IUD which can sit inside the vagina for up to four weeks or up to few years respectively. As both are used as continuous contraceptive devices, they are design to be used during sexual intercourse. While vaginal ring is self-inserted by women into the vagina similar to a tampon, the IUD device must be inserted by trained healthcare professional. Both devices, when inserted correctly, feel comfortable or women can't feel them at all.

The biggest limitation of both IUD and vaginal ring devices, for continuous pH monitoring, is their extremely small size, which makes it very difficult to accommodate all required sensor components. Moreover, both devices do not feature the string, which would hang out of the body and which could be used to host the RF antenna externally to the body. Finally, both devices should be flexible enough in order to allow to place them at the right position inside the vagina, what pose a very difficult requirement for the electronic circuit and sensors.

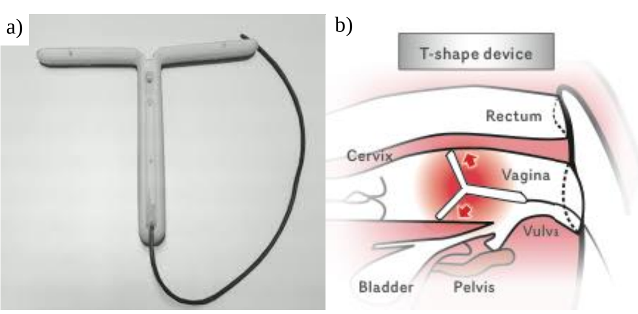

Fig. 2. a) Cattle's 'T'-shaped CIDR device: b) CIDR placement inside cattle's vagina.

2) Cattle's ph sensor housing

The size and shape of an intravaginal system is complex and dictated by the need for the insert to be flexible, change shape, expand or contract, depending upon the designers' intended administration and retention mechanism. The key design considerations, discussed in this section, revolve around it being safe to use and not cause damage to the animal.

The vaginal cavity of dairy cattle is similar to that of a human. It has different dimension and rests in the horizontal as opposed to the near vertical orientation of the human vagina. As a result of this, the ring and tampon shaped inserts, that are commonly used in humans, are unable to retain in the vagina of animals. Therefore, 'T' and 'Y' shaped inserts are typically used in animals [18].

Since farmed animals do not have the ability to self-administer veterinary drugs delivery systems, farm labour need some means by which to easily insert and control device operation. For this purposes each insert type must be accompanied by a dedicated applicator instruments which will lead and release the device into the site of measurement.

An intravaginal measurement device will only be effective if it remains at the site of measurement for the intended duration of the experiment. For this purposes each intravaginal insert must utilize an 'expansion mechanism' to retain the device in the right place inside the vagina for the duration of monitoring. The expansion of the 'wings' in 'T' and 'Y' shaped inserts retains them in position.

Finally, device administered to farmed animals requires some means of removal from the animal at the end of the monitoring period. Removal must be a simple process, be non-invasive (not require surgery) and be achieved quickly and safely, without damage to the animal. Typically removal of vaginal devices is aided by the addition of a 'tail' into the design of the device. This string, usually made of blue plastic material, should be long enough to protrude out of the vulva and extrude sufficiently to enable farm labour to grasp it firmly and pull the device out of the vagina without slippage [18]. Similar to human tampon-like enclosure it is the perfect element to accommodate transceiver's antenna.

According to Rathbone's [19] comprehensive review, there are four main types of commercially available intravaginal veterinary inserts developed for reproductive drugs administration: a) polyurethane sponges; 2) silicone based inserts such as CIDR device, presented in Figure 2; 3) electronically controlled inserts such as EMIDD and 4) a biodegradable inserts called the PCL Intravaginal Insert. In terms of use and performance, all intravaginal inserts produce the required biological responses to control the estrous cycle of farmed animals, are safe to handle and are easily inserted and removed.

As shown by Burdick et al. [15] the 'T' shaped CIDR device is of particular importance for intravaginal measurements due to its rectangular opening directly below the point, where the two arms of the 'T' shape merge. After CIDR application it is the most optimal location for pH and temperature sensor installation, which guarantee most accurate measurements, due to the central location inside the vagina, in direct contact with vaginal fluids.

D. *Sensor housing material*

Materials used for electronic biomedical device packaging must have a combination of thermomechanical, electrical, optical, chemical, and biological properties. Intended thermomechanical properties are: high flexibility, good tensile strength, good dimensional stability, low glass-liquid transition temperature (Tg), very small linear coefficients of thermal expansion (CTE), and wide operating temperature range. The electrical parameters are good dielectric strength, low dielectric constant, low dielectric losses, and solid volume resistivity. The optical considerations focus on high transparency of a material to enable system inspection. The chemical requirements are low moisture absorption and good resistance to different chemical solvents used in life sciences applications. The biological properties mean material biocompatibility defined as compatibility, that is, not causing any unwanted reaction (toxic, injurious, or any other kind) to biomaterials such as living tissue or living systems. There is an international standard (ISO 10993) to test the biocompatibility of a material. The material must be biocompatible to the levels required for the specific use. The standard ISO 10993 defines a device category, a contact regime, and a contact timescale [20]. Finally, there is a material cost consideration aimed at reducing overall system's cost.

The list of biocompatible polymer materials, that are already widely used for biomedical applications such as biochips or microfluidic devices, such as the one proposed in this paper, are: cyclic olefin copolymer (COC)/cyclic olefin polymer (COP), polyetheretherketone (PEEK), polymethyl methacrylate (PMMA) [20], as well as other materials already widely used for electronics packaging such as polycarbonates (PC), liquid crystal polymers (LCP) or even some biocompatible polilaktyds (PLA) or acrylonitrile butadiene styrenes (ABS) materials, amongst others. For prototyping purposes, the most useful polymers from this group are thermoplastics, such as ABS or PLA, which can be used as the filament of desktop 3D printers based on Fused Filament Fabrication (FFF) technology. Moreover, as polymeric material's cost is relatively low and, hence, these materials have limited manufacturability, they are also suitable for mass production.

Another very popular material type for biocompatible encapsulation is silicone. The polydimethylsiloxane (PDMS) is the most widely used silicon-based organic polymer. It is optically clear, and, in general, inert, non-toxic, and non-flammable. It is the most commonly used material for fabrication of contact lenses and medical devices. Its advantage is that it is easy to process with little or no infrastructure required. Furthermore, with development of affordable paste extruders, such as Discov3ery [21], that can be easily added to almost any existing 3D printer, that uses fused deposition modelling (FDM), the PDMS becomes an indispensable material for 3D prototyping of biomedical systems. Unfortunately, despite the abovementioned advantages, mainly because of the high cost of the raw material and material functional limitations, PDMS is not suitable for mass-scale production.

IV. Intra-vaginal pH monitoring System

The proposed high-level system architecture, presented in Figure 3, is based on a three-tier logic centered architecture for ubiquitous health monitoring discussed in [22]. It consists of three elements: the wireless pH and temperature sensor node, the smartphone device responsible for data aggregation and processing, and remote web services for data analysis. This paper focuses on the first two components, which structure and operation is discussed in the following subsections.

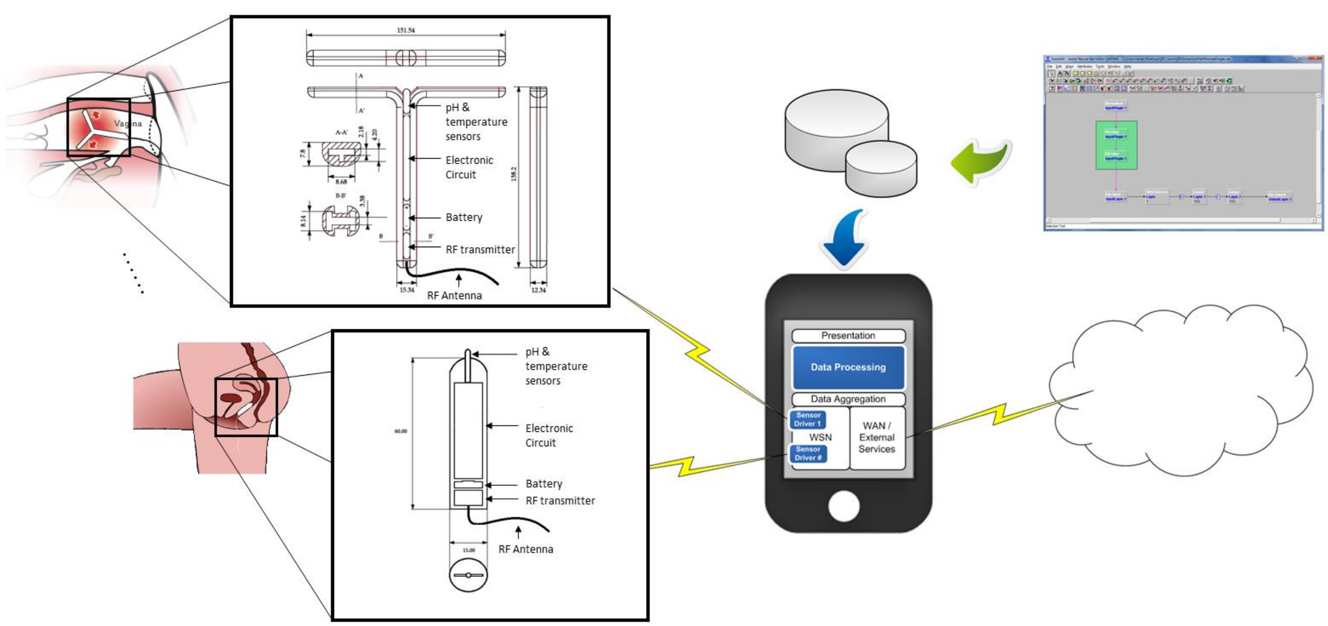

Fig. 3. System architecture and conceptual designs of the intra-vaginal pH and temperature monitoring sensors.

Proposed sensor node, presented in Figure 3, includes: pH and temperature sensors, a small PCB with ADC and microcontroller, a small rechargeable battery, and a low power radio transceiver with an external antenna. Aiming at 'one-for-all' sensor node design, it has to respect size as well as anatomic limitations of both monitoring subjects, in this case dairy cattle and human. Considering tampon-like enclosure and following medical recommendations, the human sensor has to fit in a container with about 60mm x 15mm of area. In turn, following veterinary recommendations the animal sensor has to fit inside 'T'-shaped CIDR device container with about 138mm x 15mm of area. For health and safety reasons, a margin of 2mm on both sides and 10mm on both ends should be maintained, therefore living the maximum of 40mm x 11mm of area for the sensor node with the battery.

This combination of compact packaging and long battery life running from a single coin cell was attained with the Nordic Semiconductor's ultra-low power (ULP) nRF51 series of flash-based System-on-a-chip (SoC). The nRF51 series is based on the 32 bit ARM® Cortex™ M4F CPU with 512kB flash and 64kB RAM, with configurable I/O mapping for analog and digital I/O and Nordics leading multiprotocol radio, which supports Bluetooth Smart, ANT, and 2.4GHz proprietary solutions. A key feature of the nRF51 Series and their associated software architecture is the possibility for Over-The-Air Device Firmware Update (OTA-DFU). It allows for firmware updates, bugs fixes and new features to be issued and downloaded to products in the field via the cloud. Considering the working environment and the strict opacity requirement of the proposed probe, this brings added security and flexibility to product development and maintenance. The nRF51 Series is also the most flexible wireless connectivity solution available due to its pin compatibility across protocols. It allows for drop-in replacement of device types with no requirement for redesign of circuit layout. This is also supported by its software architecture, which ensures an absolute separation between application code and protocol stacks to allow to maintain one code base for different wireless technologies.

The potentiometric pH measuring circuit consists of a passive reference electrode and active pH electrode which are both immersed in the same solution. The prototype system uses the solid state ISFET pH sensor and reference electrode from Sentron [23]. Solid state ISFET pH sensors are the sensor of choice for medical pH measurement requiring, the highest level of performance, robustness and small size. This differentiates them from conventional glass electrodes and other ISFET sensors which are fragile and / or larger in size. The active component of the pH circuit is the non-glass ISFET pH electrode encapsulated in a catheter with a diameter of 3mm and a length of 15mm, suitable for in-vivo applications. It has a range of 0.00 to 14.00 pH with accuracy of 0.01 pH and a total pH drift of 0.14 pH after 24 hours in pH 7 at 25ºC. The pH is measured as voltage output which represents the electric potential created between the electrode and the reference electrode. The reference electrode used in the prototype system is based on the potassium chloride and has a diameter of 3 mm and a length of 30 mm. This KCl solution is in contact with the specimen via a porous Teflon diaphragm. The function of the reference electrode is to provide a constant potential regardless of the composition of the solution it is placed in. Complementary, analog front-end module, used for signal conditioning, has an uncalibrated analog pH output signal with a voltage output 0 - 3.3 V of ~ 52 mV / pH and pH 7 between 500 mV and 1800 mV. It produces a high current, low impedance output at the ADC channel and allows for the use of connecting cables without excessive shielding.

Moreover the pH sensor module contains a PT1000 temperature sensor in addition to the ISFET pH sensor chip, which is used for the pH temperature compensation. It is a PTC type thermistor used for precise temperature monitoring applications, where the errors in measurement have to be excluded. The linear relationship of the resistor to temperature, simplifies its use in many electronic applications. All three components - pH electrode, reference electrode and temperature sensor are embedded on top of the tampon-like enclosure for female, and in the rectangular opening of the 'T' shape CIDR enclosure, for cattle.

The prototype system is powered by the Lithium AFP1801 battery from Panasonic. It is a rechargeable, circular shape battery measuring only 11.6mm x 10.8mm with a relatively large capacity of 160mAh for its operational model. As the system is design to operate in the synchronous mode with measurements taken at given time intervals, the probe will spend most of the time in low-power state, waking up only when readings and transmissions are required. In the low-power state the CPU in ON mode consumes only 1.6µA of power, while the running CPU consumes only 52µA of power per MHz what, considering the maximum CPU clock rate of 64MHz, accounts for the total processing power consumption of 3.3mA. The peak power consumption occurs in the radio transmission mode in which the board consumes 5.4mA and 7.5mA of power for radio Rx and Tx respectively. Considering synchronous operational model and the low-power consumption profile, the selected battery will support a long operational lifetime for the prototype system. In order to ensure a regular voltage of 3V on the system, the battery is connected to the circuit board through the voltage regulator.

V. FUTURE WORKS AND CONCLUSIONS

Design presented in this paper is the conceptual model of the intra-vaginal pH and temperature monitoring device, which has not yet been tested in the field. Therefore the future work on this project will concentrate on device testing and validation through experimental monitoring of 3 dairy cattle over the period of 1 month. Over this period of time, a number of additional observations by veterinary specialists and laboratory tests on independently collected vaginal swabs will be performed at regular time intervals. It will be performed to select and optimize the most appropriate method(s) of monitoring and to perform sensors' validation on independently sampled referential vaginal swabs. The detailed veterinary examination will be performed to assess the physiological status of genital tract of each cow included in the experiment.

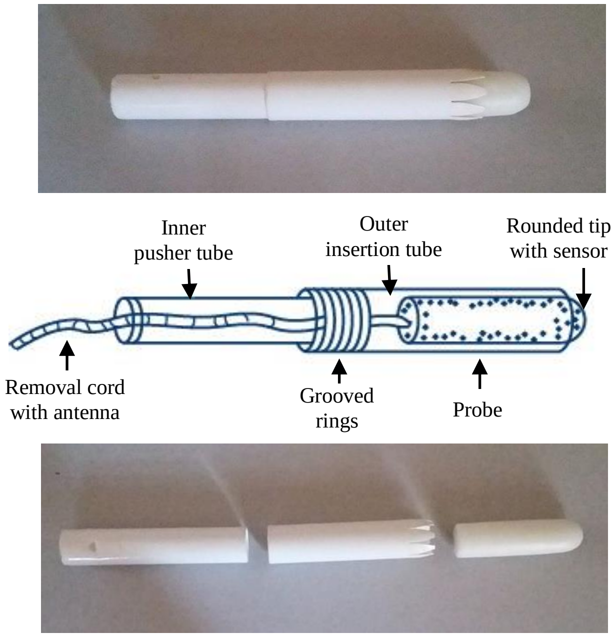

Fig. 4. 3D printed sensor enclosure with applicator.

Observations and results from the animal experiment will be further used to refine the design and improve the calibration of the pH sensor for human. For this purpose following our successful print of dummy tampon-like female's sensor enclosure, presented in Figure 4, we will further evaluate various methodologies for 3D printing in silicone material. Furthermore, due to silicone properties, once the device is printed, it will not allow for further battery replacement. Therefore, as part of future works, various wireless battery charging solutions will be evaluated and integrated in the sensor probe design.

Better understanding of vaginal pH and temperature variations, combined with the accurate and timely monitoring using intra-vaginal sensor device proposed in this project, have a great potential in veterinary to improve early detection and early notification of heat in animals as well as in human gynaecology to support illness prevention and early detection, enabling women's self-management of wellness.

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