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Electrode Interfaces for Bilirubin Monitoring

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Abstract: *The transcutaneous billirubinometer have existed for over 30 years but the clinical utility of the technique is limited to a screening method for hyperbilirubinemia, rather than a replacement for invasive blood sampling. The reason for this limited clinical value and address possibilities for improvement to be analyzed. A method and apparatus for the determination of bilirubin concentration in tissue such as skin particularly neonatal skin, light reflected from the skin under test is analyzed to determine bilirubin concentration in the skin. This concentration depends on the optical property of the skin and the amount of bilirubin in the blood.*

Keywords: *Transcutaneousbillirubinometer, hyperbilirubinemia, bilirubin, neonatal skin.*

I. INTRODUCTION

Noninvasive bilirubin monitoring technology has advanced tremendously over the years making a substantial impact on medical diagnostics and personal healthcare, from the early fundamental advances in noncontact and dry sensing technology to most recent advances extending the range of physiological sensing using imaging and electrical sensing technology abundantly available in handheld devices and household appliances. CMOS technologies and circuit techniques have facilitated the development and miniaturization of innovative physiological sensing devices, improving the performance, power and monetary costs while ensuring the validity of medical information through analog and digital signal processing methods. These IC developments have permitted reliable noninvasive measurement of vital parameters and have spawned a variety of new instruments for clinical treatment and diagnosis. Innovations by semiconductor technologies enable ambulatory continuous-time monitoring of patients even at home. This ubiquitous monitoring supported by modern IC technology can enable personalized healthcare and preemptive medicine, which are emerging solutions to soaring healthcare costs induced by the current demographical trend of increasing aging population. The patient-supporting sensors and systems not only extend the capability and accuracy of modern diagnostics, but also improve the patient's everyday life. In addition, miniaturized electronic systems for biosignal sensing can be tailored to many nonclinical applications such as sports and entertainment. The main functional components of a generic IC for noninvasive bilirubin monitoring, comprising Gallium nitride LED, photo detector BPW 34, analog to- digital converter (ADC), digital signal processor (DSP), radio frequency (RF) communications, and power management. Foremost, a solid and thorough understanding of the electrode– body interface is of primary importance for accurate and reliable noninvasive bilirubin sensing and signal acquisition. The following section reviews fundamentals of electrode–body and optrode–body interfaces for biopotential acquisition, impedance measurement, and optics-based sensing.

II. Literature Review

1. R. Sarpeshkar, T. Delbruck, and C. A. Mead, "White noise in MOS transistors and resistors," IEEE Circuits Devices Mag., vol. 9, no. 6, pp. 23–29, Nov. 1993.

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In 1993, an apparently healthy white boy was born at 37 weeks' gestation weighing 6 lbs, 13 oz (3090 g). Delivery was uncomplicated. His 1 minute and 5 minute Apgar scores were eight and nine, respectively (normal range: seven10). His mother's blood type was O+, and the newborn was A+, Coombs negative. On discharge at 20 hours, he was alert and nursing well; a 2week follow-up appointment was scheduled at a pediatric clinic. On day 9, the infant was taken to a pediatric clinic with jaundice. The condition was thought to be the result of breastfeeding. That evening, he exhibited lethargy, was not nursing, and had "pumpkin orange" skin coloration. On day 10, the parents notified their physician about the infant's lethargy and poor eating and were given an appointment for the following morning. During a pediatric appointment on day 11, the infant weighed 5 lbs, 10 oz (2552 g), was dehydrated, and jaundiced. A tested serum sample revealed an elevated bilirubin of 41.5 mg/dL (normal range at age >72 hours: <17 mg/dL). Despite treatment with phototherapy and two double volume exchange transfusions, on day 11, he developed athetosis, oral motor dysfunction requiring a gastrostomy tube, and dental dysplasia. Kernicterus was diagnosed at age 6 months.

2. C. C. Enz and G. C. Temes, "Circuit techniques for reducing the effects of op-amp imperfections: Auto zeroing, correlated double sampling, and chopper stabilization," Proc. IEEE, vol. 84, no. 11, pp. 1584–1614, Nov. 1996.

In 1996, an apparently healthy white boy was born at 37 weeks' gestation weighing 6 lbs, 5 oz (2863 g). Apgar scores were eight and nine at 1 and 5 minutes, respectively. At 17, 23, and 33 hours, jaundice was noted. No serum bilirubin level or ABO or Rh status was disclosed. Examination revealed normal neurologic and physical findings, and he was discharged after 36 hours; a follow-up appointment at a pediatric clinic was scheduled at 1 week. On day 4, the patient exhibited lethargy and poor breastfeeding. On day 5, he was admitted to a hospital. Laboratory findings included a bilirubin level of 34.6 mg/dL, and phototherapy was started. Later that day, the patient developed opisthotonus, a high-pitched cry, and poor suckling and later developed athetoid cerebral palsy, hearing loss, and gaze paresis. Kernicterus was diagnosed at age 18 months.

3. C. Menolfi and Q. T. Huang, "A low-noise CMOS instrumentation amplifier for thermoelectric infrared detectors," IEEE J. Solid-State Circuits, vol. 32, no. 7, pp. 968–976, Jul. 1997.

In 1997, an apparently healthy white boy was born at 37 weeks' gestation weighing 8 lbs, 2 oz (3686 g). His Apgar scores were nine at 1 and 5 minutes. On discharge at 22 hours, cephalohematoma and heart murmurs were noted. The following day, the infant was taken to a pediatric clinic where examination found jaundice but no heart murmur. Fifteen minutes of sunlight per day was recommended as treatment. During the next 4 days, the infant developed lethargy and poor breastfeeding. On day 6, he was taken to a pediatric clinic where a serum sample was drawn and tested. Results included a bilirubin level of 27 mg/dL; Phototherapy was started. By 11 p.m., the patient's bilirubin peaked at 33.4 mg/dL, and he received an exchange transfusion. During the next 4 months, he developed athetoid cerebral palsy, oral motor dysfunction requiring a gastrostomy tube, and gaze paresis. Kernicterus was diagnosed at age 4 months.

4. C Menolfi and Q. T Huang, "A fully integrated, untrimmed CMOS instrumentation amplifier with sub microvolt offset," IEEE J. Solid-State Circuits, vol. 34, no. 3, pp. 415–420, May 1999.

In 1999, an apparently healthy white boy was born at 39 weeks' gestation weighing 9 lbs, 8 oz (4313 g). Pregnancy was unremarkable but delivery required vacuum extraction. His Apgar scores were eight and nine at 1 and 5 minutes, respectively. AO blood incompatibility was noted and Rh status was unknown. At 22 hours, he appeared jaundiced; At 52 hours, he was discharged with the treatment recommendation that he receive sunlight. The infant was alert and nursed well during the next 11 days. However, at his follow-up examination on day 12, he appeared jaundiced.

The initial serum bilirubin level was 23.6 mg/dL, which peaked at 29.4 mg/dL. The same day, the infant was admitted to a hospital for phototherapy. During the next 4 months, he developed athetoid cerebral palsy, hearing loss, and enamel hypoplasia, and kernicterus was diagnosed at age 4 months.

5. K. Li and S. Warren, "A wireless reflectance pulse oximeter with digital baseline control for unfiltered photo plethysmograms," IEEE Trans. Biomed. Circuits Syst., vol. 6, no. 3, pp. 269–278, Jun. 2012.

In 2012, Bilirubin is measured in serum or plasma, although its detection in urine (using dipsticks) is also informative. Non-invasive transcutaneous photometric measurement at point of care using a dedicated instrument 'billirubinometer' is practised in infants to guide the need for blood to be drawn to guide treatment for neonatal jaundice. Bilirubin is photosensitive, and specimens should be protected from light when highly accurate measurements are required. This is especially important with specimens collected from neonates.

Limitations

1. Serum [bilirubin] can be elevated to at least 50 μmol/L without jaundice being clinically apparent.

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2. Neither hepatic nor biliary disease invariably causes an increase in serum [bilirubin].
3. An increase in serum [bilirubin] is not specific to hepatobiliary disease; it can occur in haemolytic conditions or conditions of ineffective erythropoiesis. The excess bilirubin in these instances is unconjugated.

III. Our Proposal

In current year following detection methods are used.

1. Diazo Methods

These are based on reaction with diazotized sulfanilic acid (the diazo reagent) to produce two colored azodipyrroles that can be measured spectrophotometrically, either at 530 nm or, after addition of alkaline tartrate, at 530 nm The reaction is accelerated by alcohol and a variety of other 'accelerators' (e.g. sodium benzoate) that cause the dissociation of unconjugated bilirubin from albumin. In the presence of an accelerant, both conjugated (including delta) and unconjugated bilirubin (together comprising total bilirubin) are measured; this is also termed 'indirect' bilirubin. In the absence of an accelerant, only the conjugated ('direct') bilirubin is measured. The difference is considered to be a measure of unconjugated bilirubin. It is important that no unconjugated bilirubin reacts in 'direct' methods: this can be avoided by maintaining a reaction pH of ~1.0.

2. High Performance Liquid Chromatography (HPLC)

HPLC methods are capable of measuring the various bilirubin fractions present in plasma separately. This can be achieved using a Micronex RP-30 column but for practical purposes the use of direct and indirect diazo techniques provides sufficient clinical information for diagnostic purposes.

3. Enzymatic

These methods employ the enzyme bilirubin oxidase (EC1.3.3.5) to convert bilirubin to biliverdin. The reaction is followed by measuring the fall in absorbance at 425 or 460 nm. Separate quantization of the different species of bilirubin is achieved by using different reaction pH conditions.

4. Spectrophotometric

This method involves the measurement of absorbance at 437nm, the maximum absorbance of bilirubin. This is the basis of the method used in billirubinometer.

During current method a small amount of your blood is needed to perform this test. The blood sample is obtained through venipuncture, where a needle is inserted into a vein through the skin in your arm or hand, and a small amount of blood comes out through the needle into tubing and is stored in a test tube. For this test, you will need to fast (not eat or drink anything other than water) for four hours before you have the test performed. Drink a normal amount of water before going to the laboratory or collection site. When the blood is collected, you may feel some moderate pain or a mild pinching sensation, though this is usually very short in duration and very slight. After the needle is taken out, you may feel a throbbing sensation, and you will be instructed to apply pressure to the site where the needle entered your skin. A bandage will be applied that needs to remain in place typically for 10 to 20 minutes, and you should avoid using that arm for heavy lifting for the rest of the day.

There are some very rare risks to taking a blood sample:

1. Lightheadedness or fainting
2. Hematoma—a bruise where blood accumulates under the skin
3. Infection—usually prevented by the skin being cleaned before the needle is inserted
4. Excessive bleeding—Bleeding for a long period afterward may indicate a more serious bleeding condition and should be reported to your doctor.

The coupling of biopotential signals from the body into the front-end amplifier is accomplished through electrodes. At a fundamental level, the electrode interfaces ionic currents in the body with electrical currents in the electronic instrumentation. In practice, because the electrode comprises the first stage of the signal chain, its properties can dominate the overall noise and performance of the acquisition system making its design and selection crucially important. There exist three classes of biopotential electrodes in the literature: wet, dry, and noncontact. All types of electrodes ideally measure the exact same biopotential signals.

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Wet electrodes are the most common type and considered the "gold standard" for both clinical and research applications. A typical wet electrode consists of a silver–silver chloride (Ag/AgCl) metal that is surrounded by a wet or solid hydrogel, containing chloride.

Dry electrodes operate without the use of an explicit wet/gel coupling media. The metal in the electrode directly contact the skin to couple biopotential signals. However, virtually all dry electrodes still rely on some degree of moisture which is gathered from the environment or emitted from the body (e.g., sweat). Compared with the wet electrodes, the performance of a dry electrode usually increases over time as more moisture permeates the skin electrode interface resulting in increased coupling.

The final type of electrodes, noncontact, can be thought of as a special case of dry electrodes. They operate not only without gel, but also through an insulation layer such as clothing, enabling signal acquisition without direct skin contact. As expected, the coupling impedance can be very high on the order of tens of picofarad in parallel with hundreds of mega ohm. Obtaining acceptable signals requires the use of special, very high input impedance active electrodes. Because there is no direct skin contact, movement artifacts are a major, unsolved issue especially for ambulatory use. Noncontact electrodes are also highly sensitive to environmental conditions such as humidity and the exact insulating material.

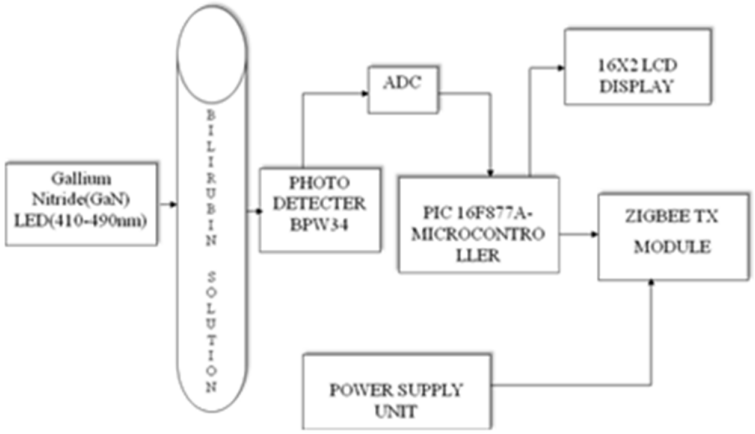
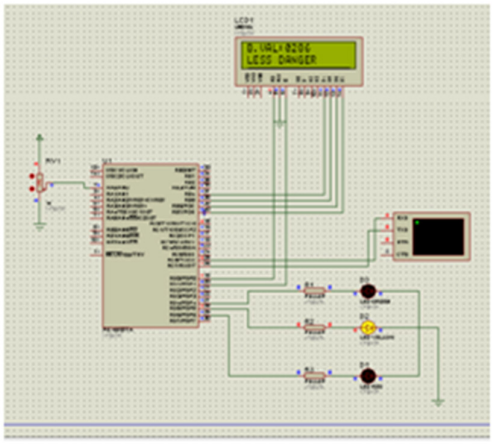


Fig 1. Transmitting unit

Light from light-emitting diodes (LEDs) at (410 - 490) wavelength is shined upon a body area with good perfusion, and quantification of either the transmitted or reflected light is done to calculate absorbance through the tissue by a photodiode. Recently, advances in integrated silicon avalanche photodiodes have dramatically improved the performance and wearability. The biopotential signal should be sensed simultaneously. Photodiode sense the incoming light and convert the current driven by the sensor into a voltage. Finally, the value becomes digitization. The value is compare to the predefined value. The corresponding result will display in the LCD screen.

IV. Software Result



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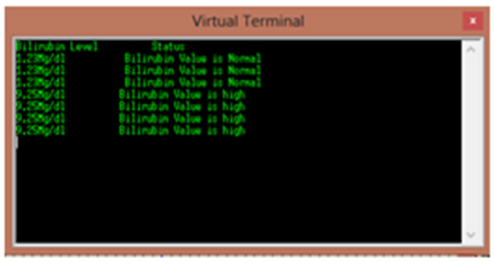

Fig2. Simulation output in less danger condition

V. Advantages

- Detects the severity of Jaundice.
- It can be configured remotely, whenever new infants are admitted
- Continuously monitors using LED and gives the test result without taking blood from heel of the child
- These LEDs emit light within the peak absorption range of bilirubin, are low cost
- Long operational lifespan when compared to existing.

VI. Applications

- Used in hospitals for monitoring infants.

VII. Conclusion

The performance of our billirubinometer is comparable to existing devices. The limited clinical value of current billirubinometer can be explained by the low blood volume fraction in the skin volume that is probed by these devices. Because the cutaneous bilirubin concentration depends for over 99% on the contribution of extra vascular bilirubin, it is a physiologically different parameter from the total serum bilirubin concentration. Hence, the standard method of evaluation that compares the cutaneous bilirubin concentration to the total serum bilirubin concentration is insufficient to fully investigate the clinical value of billirubinometer, i.e., their predictive value for kernicterus. We suggest that the clinical value may be improved considerably by changing either the method of evaluation or the technological design of billirubinometer. By using our concept the bilirubin concentration volume ranged from 0.1%.

VIII. References

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2. K. Li and S. Warren, "A wireless reflectance pulse oximeter with digital baseline control for unfiltered photo plethysmograms," IEEE Trans. Biomed. Circuits Syst., vol. 6, no. 3, pp. 269–278, Jun. 2012.
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6. R. Sarpeshkar, T. Delbruck, and C. A. Mead, "White noise in MOS transistors and resistors," IEEE Circuits Devices Mag., vol. 9, no. 6, pp. 23–29, Nov. 1993.

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