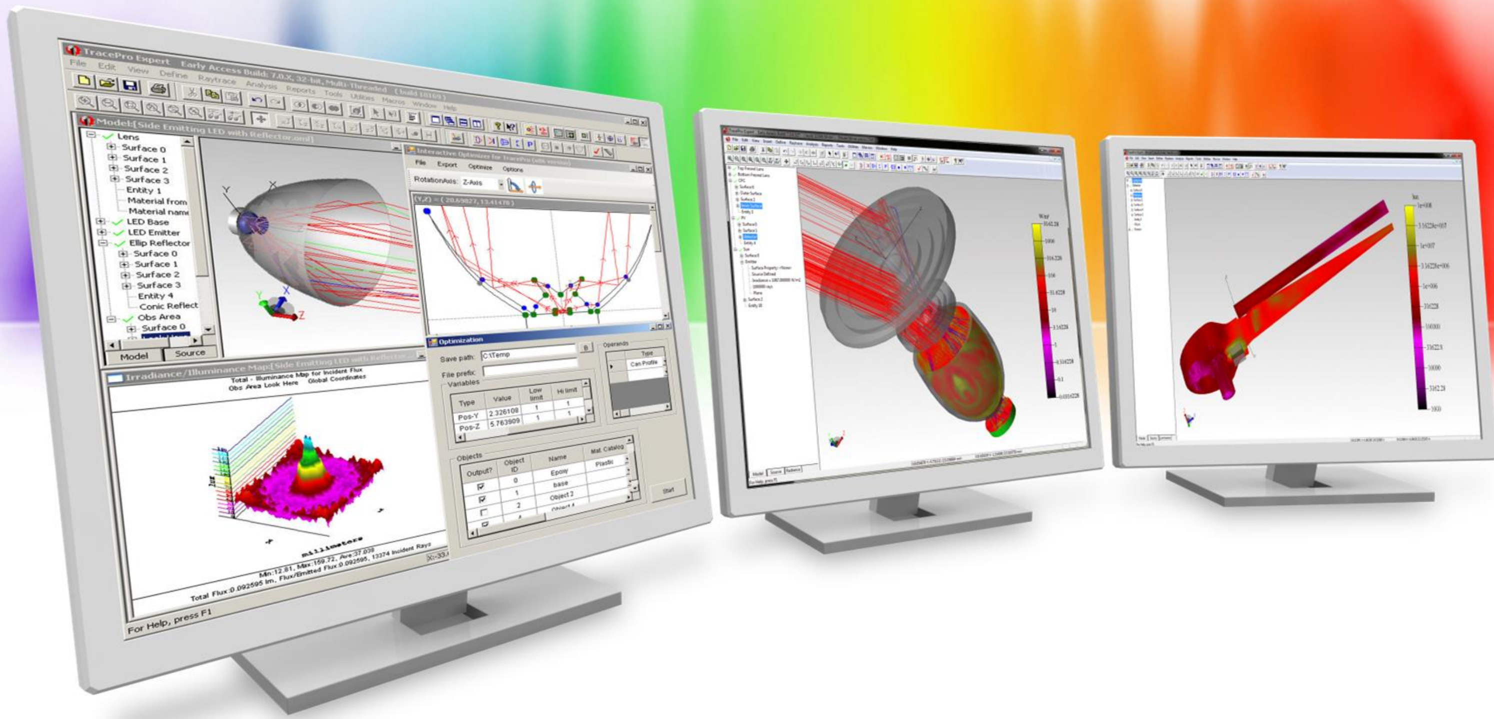

VIRTUAL SIMULATION FOR PULSE OXIMETRY WEARABLES

Presented by :
Lambda Research Corporation
25 Porter Rd.
Littleton, MA 01460
www.lambdares.com

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TracePro

- Accurate
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Agenda

- Medical Device engineers and scientists have multiple challenges designing devices for pulse oximetry. In this webinar we well investigate both transmissive and reflective pulse oximetry designs.
- We will first look at general background to understand the optical principles in pulse oximetry designs.
- To investigate throughput, cross talk and stray light issues we will use the CAD engine based TracePro® to do virtual prototyping using software simulation. Virtual prototyping is now the industry standard for expediting designs in pulse oximetry devices.
- A full demonstration using two examples will be given to show both a transmissive and reflective pulse oximetry system using the TracePro simulation software.

Background

Pulse oximetry has been used since the 1970s, and has been widely adopted by hospitals to monitor oxygen (O_2) saturation and pulse rate (PR) by attaching devices to a patient's fingertip, forehead, foot or earlobe. The application for these devices has remained stagnant for more than 40 years. Now, the growing interest in "wearables" that track health and fitness has taken pulse oximetry out of the hospital and into the general consumer market.

Medical device engineers and scientists developing these innovative pulse oximetry devices have unique design challenges: balancing measurement accuracy with stylish form factors that are desirable to the wearer. Prototyping these devices is costly and time consuming. What device engineers require is a more efficient method of accurately simulating the intensity of light being absorbed by human tissue.

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Transmissive and Reflective Methods

There are two current methods of pulse oximetry:

- Transmission - Devices using the transmission method have a vertical orientation between the LED source and the photodetector. The light (red and infrared) passes through or is blocked by the tissue in between the two optical elements.

- Reflectance. The reflectance method requires the LED source and the photodetector to be on the same surface, where the light passes through the tissue at a set angle. In the case of wearables using the reflectance method, this surface may be concave, making the angle between the optical elements variable.

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Basics of Pulse Oximetry

Both oxygenated and deoxygenated blood have different light absorption characteristics when illuminated with red and Infrared wavelengths. Doing a ratio of the light transmitted through the measurement tissue which is then received at a photodetector, Red/IR of oxygenated versus deoxygenated blood for the red and infrared wavelengths gives an estimate of the oxygen saturation of the blood. The ratio of the SpO_2 ratio is then compared to a look-up table based on a calibration curve derived from healthy subjects. In general a Red/IR ratio of .5 approximates to a 100% SpO_2 ratio. A 2.0 ratio equates to a 0% SpO_2 level[1]. Wavelengths of .660 microns and .940 microns are the most widely used wavelengths for pulse oximetry. More wavelengths have been proven to more accurately predict SpO_2 ratio.

The formula for determining the ration of SpO^2 is:

$$\text{Ratio} = \frac{\text{(power on photodiode in Red wavelength)/(power out of Red LED)}}{\text{(power on photodiode in IR wavelength)(power out of the IR LED)}}$$

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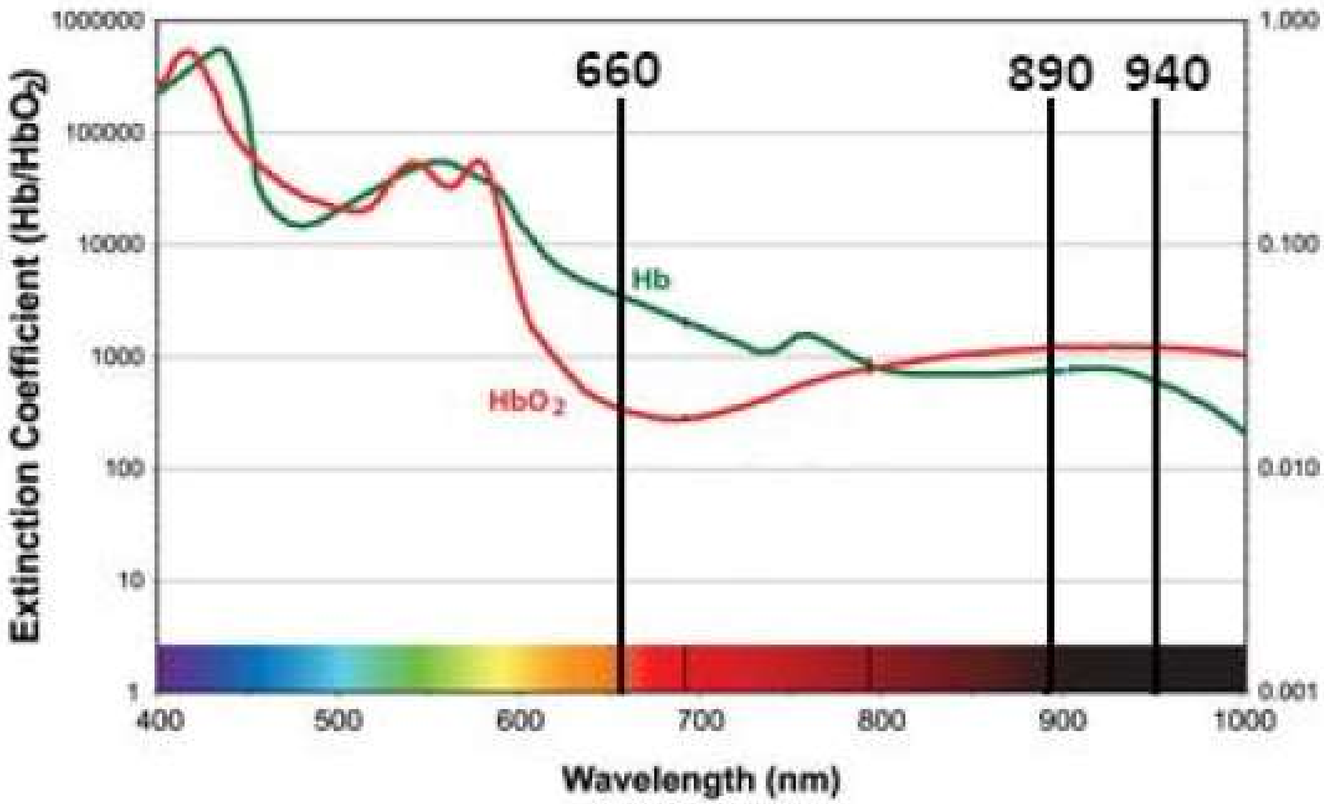
Basics of Pulse Oximetry



The light absorption characteristics of HbO2 (oxygenated hemoglobin) and Hb (deoxygenated hemoglobin)[2]

Basics of Pulse Oximetry

When measuring SpO_2 ratio there are multiple factors such as skin, tissue, venous blood, and the arterial blood to contend with. Each heart beat contracts the heart and pushes out a surge of oxygenated blood to the arteries. This increases arterial blood volume through the veins and into the tissue. Thus more light is absorbed during this surge stage. If light signals received at the photodiode are looked at 'as a waveform', there should be peaks with each heartbeat and troughs between each heartbeat. If the light absorption at the trough (which should include all the constant absorbers) is subtracted from the light absorption at the peak then, in theory, the resultants are the absorption characteristics due to added volume of blood only; which is arterial. Since peaks occur with each heartbeat or pulse, the term "pulse oximetry" was coined. This understanding solved many of the problems inherent to oximetry.

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Challenges

- Medical device engineers and scientists developing pulse oximetry devices have unique design challenges: balancing measurement accuracy with stylish form factors that are desirable to the wearer. Prototyping these devices is costly and time consuming. What device engineers require is a more efficient method of accurately simulating the intensity of light being absorbed by human tissue.
- Precise measurement of O_2 saturation and Pulse Rate (PR) requires an understanding of the absorbance of each wavelength of light in proportion to the concentration of tissue and blood, as well as in proportion to the length of the light path. An additional factor is the reduction of the bias in these measurements in order to improve accuracy, which can vary greatly based upon: 1) low levels of saturation and concentration brought on by anemia or other vascular conditions; 2) the quality of the signal to noise ratio between the device optical elements.
- Stray light in the device itself can lead to false readings. Minimizing stray light should be one of the major objectives of any pulse oximeter design.

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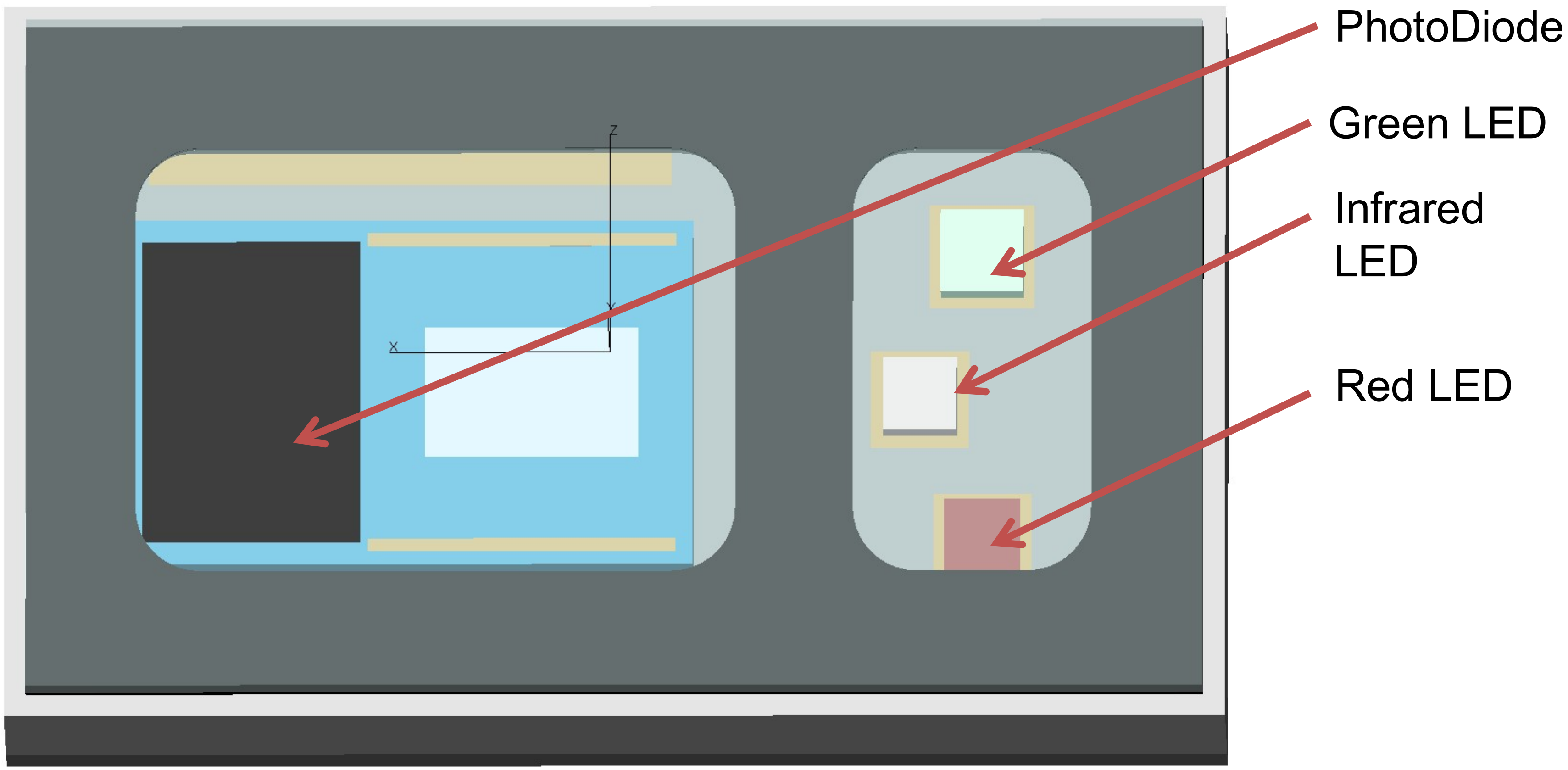
A quick look at a couple of the available off-the-shelf bio-sensors which can be used in a reflective wearable, the first Maxim Integrated, and the second from Osram. Also a quick look at the first wrist wearable that is reported to shortly have oxygen content capability. Finally a generic TracePro biosensor model is introduced.

LED and Sensors used in this webinar – Maxim MAX3010x Integrated Pulse Oximeter and Heart Rate Sensor[3]



Maxim Integrated has an all-in-one sensor featuring three LEDs emitting at 880 (infrared), 660, and 537 (green) nanometers and a photodiode in an extremely small package, 5.6mm x 3.3mm by 1.55mm with a light barrier to block optical crosstalk.

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LED and Sensors used in this webinar – Osram BioMon sensor – Osram SFH-7060[4]

Picture of an actual SFH-7060 Biomon Sensor

LED supplier OSRAM has its own all-in-one sensor featuring three LEDs emitting at 940 (infrared), 655 (red), and 530 (3x green) nanometers and a photodiode in an extremely small package, 4.7mm x 2.5mm by .9 mm with a light barrier to block optical crosstalk. This OSRAM biosensor is a good off-the-shelf component to monitor pulse rate and provide pulse oximetry information for a wearable.

Closest known wearable using off-the shelf biosensor, Tom Tom - Spark

Image courtesy of dcrainmaker.com[5]

The Tom Tom Spark uses the Osram SFH-7060 optical biosensor. Currently the Spark can only measure Heart Rate but they are working to provide VO_2, oxygen consumption, using a firmware update. A paper on the development issued by LifeQ in April 2016 showing results for VO_2 can be found at: http://lifeq.com/wp-content/uploads/2016/06/LifeQ_VO2_v1.0_Q2-2016.pdf

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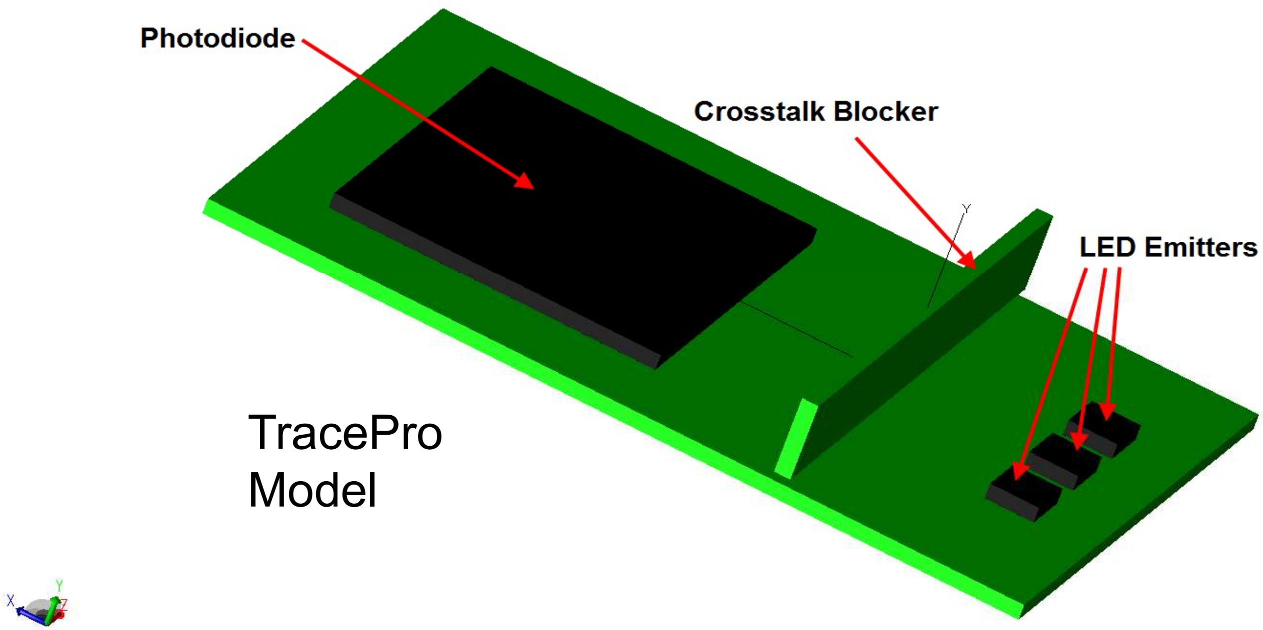
TracePro Model used in this webinar for the reflective wearable example



For this webinar, I have created a TracePro generic biosensor model with three LEDs emitting at 940 (infrared), 655 (3X red), and 530 (green) nanometers and a photodiode in an small package, 5mm x 2.5mm by 1mm with a light barrier to block optical crosstalk.

Design Problems in Wearable Pulse Oximeters

- False Signal Due to Stray light issues of the device or from external sources like the sun
- Problems due to design constraints and positioning problems on the skin or tissue
- Movement artifacts of the wearable directly due to an athlete running, or the wearable moving or bouncing due to strenuous exercise and sweating.
- Inadequate blood flow due to the wearable constraining the blood flow
- Degradation of the wearable materials over time causing degradation that could cause external sources to reach the photodiode of the pulse oximeter sensor
- Measurement sights like fingers are quite good for a measurement site for SpO_2 determination but the wrist area had poor perfusion index (ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue).

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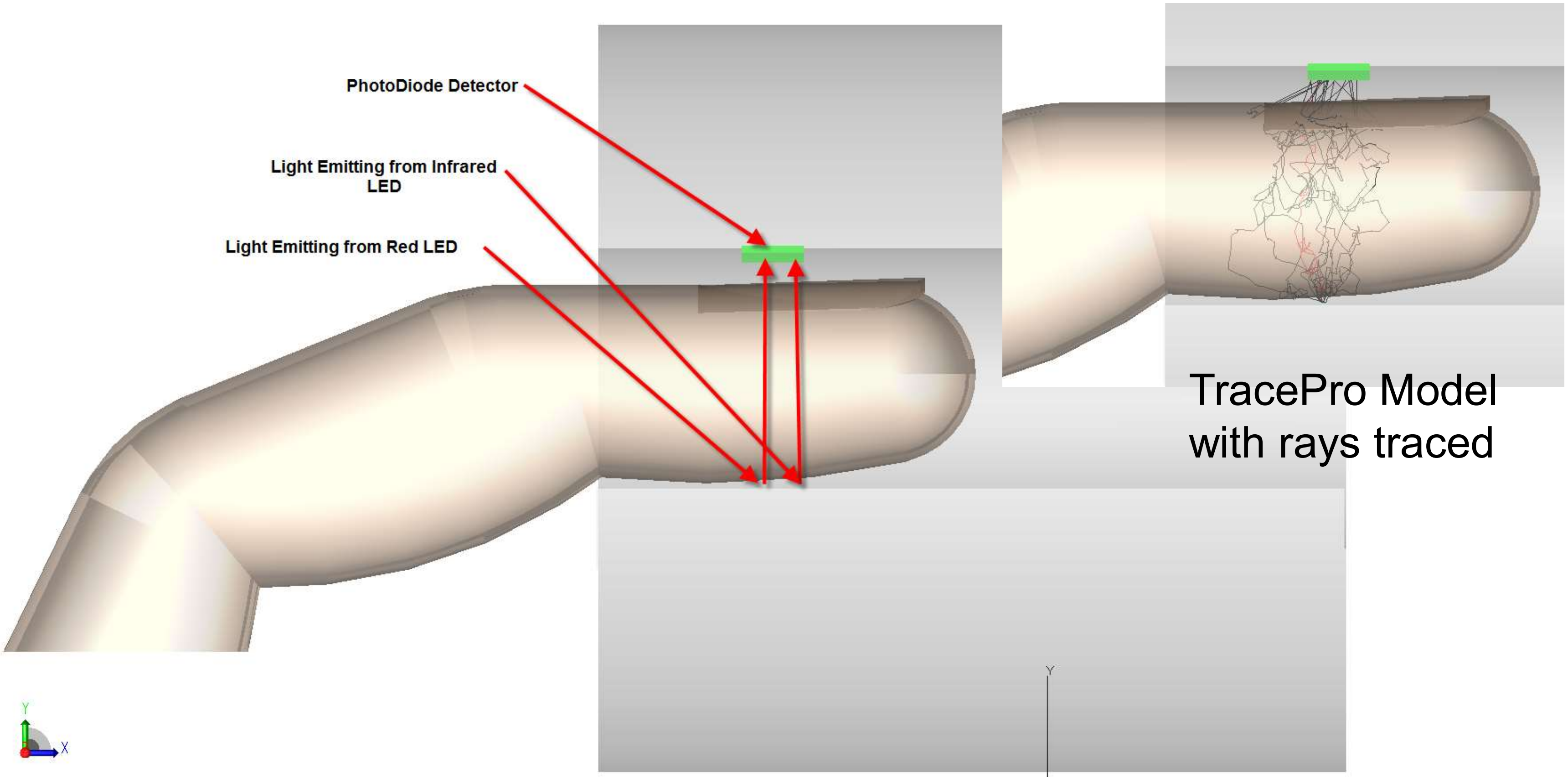
First Example
Transmissive Finger Pulse Oximeter

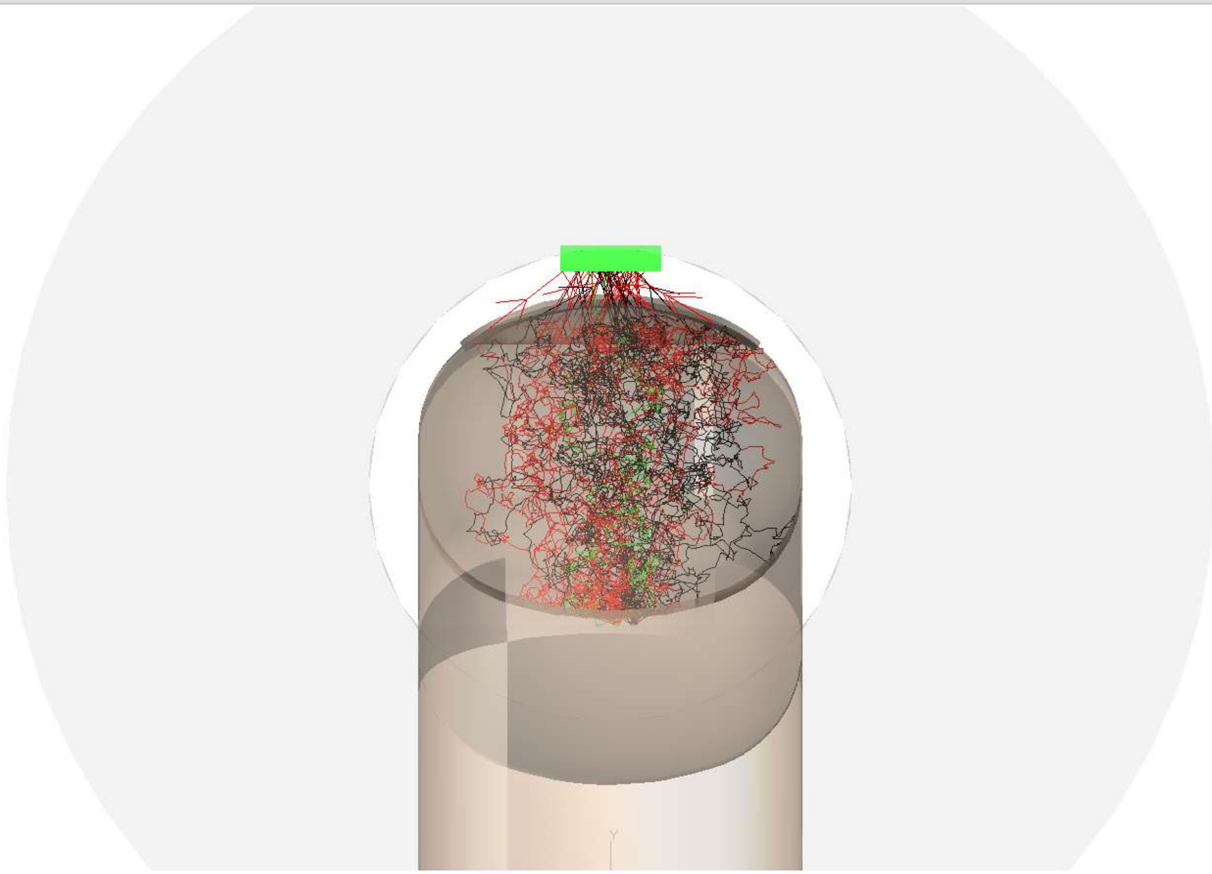
Transmissive System – Finger Pulse Oximeter



TracePro Model with rays traced

This device uses transmission to propagate either two or three LEDs positioned on the bottom of the device to emit through the finger to the photodiode detector situated in the top of the device. Above shows the general method, top inset at right shows the actual ray trace in TracePro

Transmissive System – Finger Pulse Oximeter



Looking at an end-on view of the same ray trace for the rays that reach the finger, we can see the route the rays take quite easily. While this may not look it, this is actually a good thing, since the bone in the finger blocks light. This ray trace shows that due to bulk scattering in the tissue light can travel around the bone and reach the photodiode.

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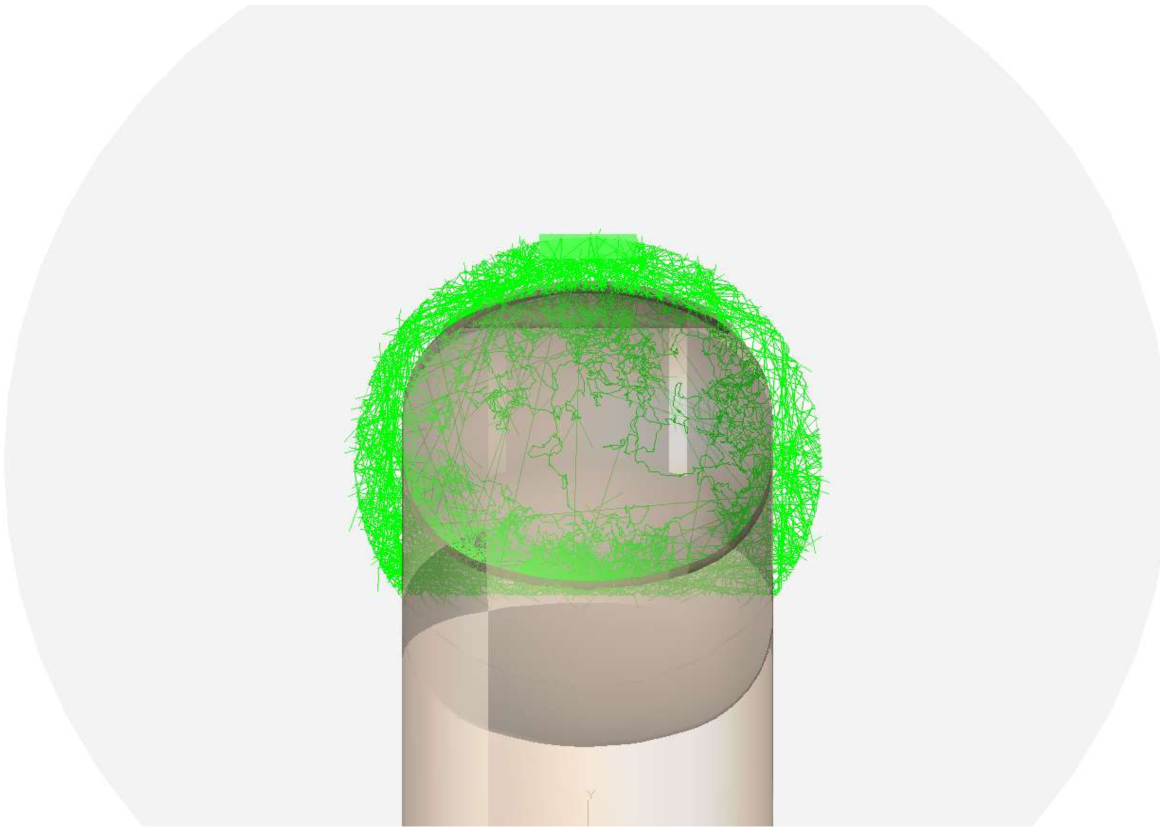
Transmissive System – Finger Pulse Oximeter



This simulation only uses the Red emitting LED as a source for ease of demonstration. As seen in figure above, light emits out of the Red LEDs and reflects around the inside of the pulse oximeter's plastic white reflective surface to reach the photodiode. In this case, the stray light far supersedes the actual propagation of the light propagating through the finger tissue, which would create a false reading.

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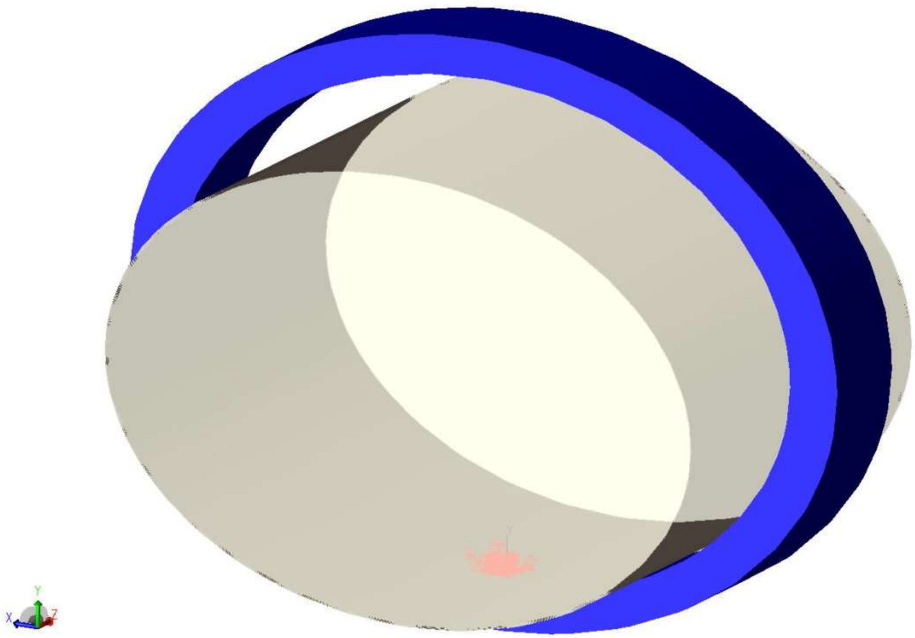
Second Example
Reflective Wrist Wearable Example

Reflective Pulse Oximeter Example – Wrist Wearable



The second example pulse oximetry system is the reflective wearable. In this system light is emitted using either a two or three wavelength biosensor and enters the tissue following a banana shaped light path to reach the photodiode on the same surface as the LED emitters. The cross talk barrier in-between the LEDs and biosensor is crucial to stop the direct stray light path.

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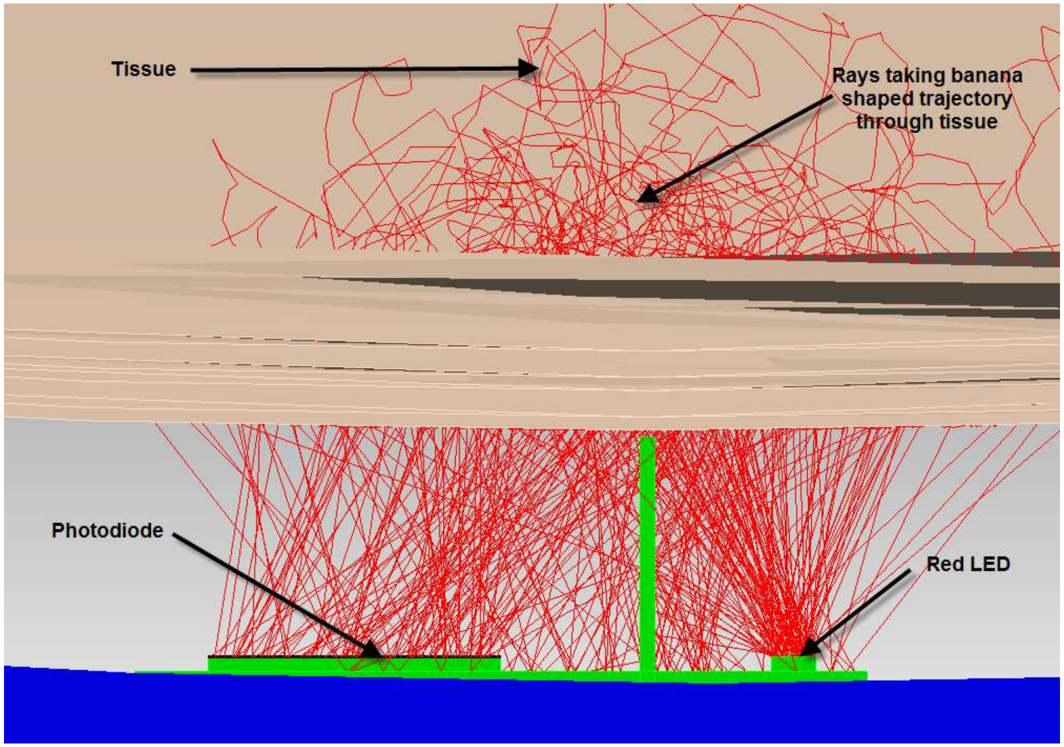
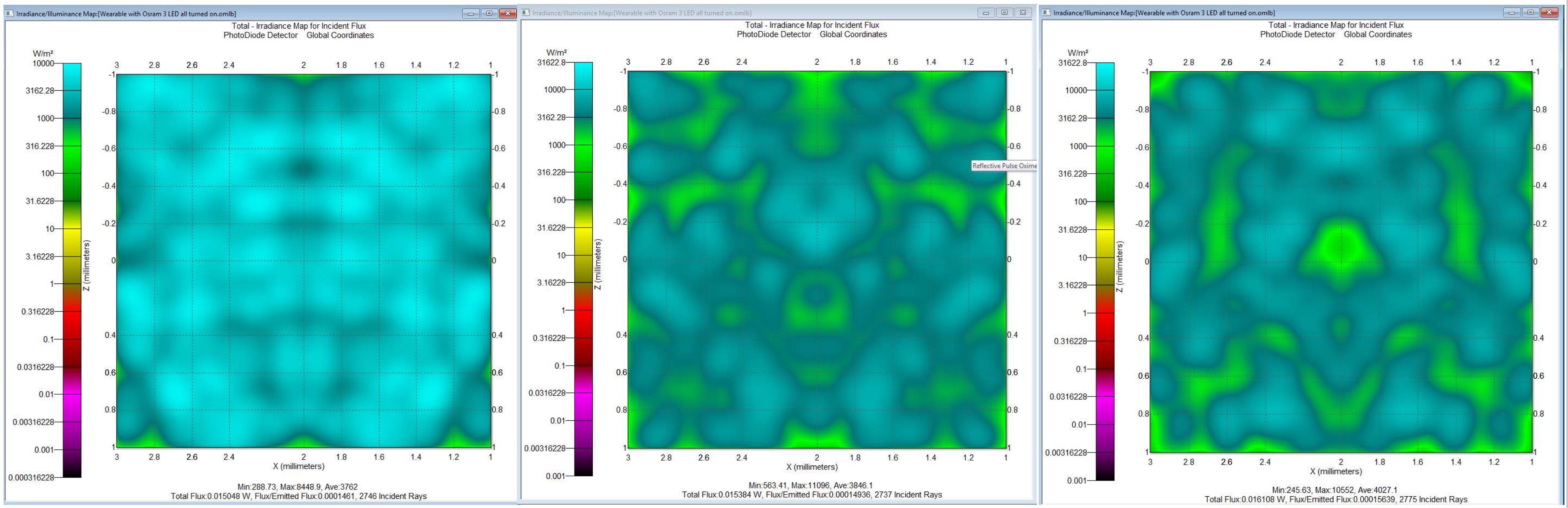
Reflective Pulse Oximeter Example – Correct path through tissue



The path that we want light to take is to have light enter the oxygenated tissue and bulk scatter to the photodiode. This plot shows only the contribution from the Red LED using TracePro's ray sorting per source. In the above figure the Red LED light enters the skin and bulk scatters through a banana shaped trajectory to reach the photodiode. The crosstalk barrier has been extended in this simulation to block internal and external stray light paths.

Reflective Pulse Oximeter Example – Correct path through tissue irradiance results for each LED source



The irradiance maps for light entering the tissue and bulk scattering towards the photodiode are shown above for the Green on far left, Red in the middle and IR on the right. Total flux for the green LED contribution is .015Watts shown in the left irradiance map, .0153Watts for the red in the middle and .016Watts for the IR on the far right. This throughput makes sense due to the fact that light transmits better through tissue as wavelength increases from the visible into the IR.

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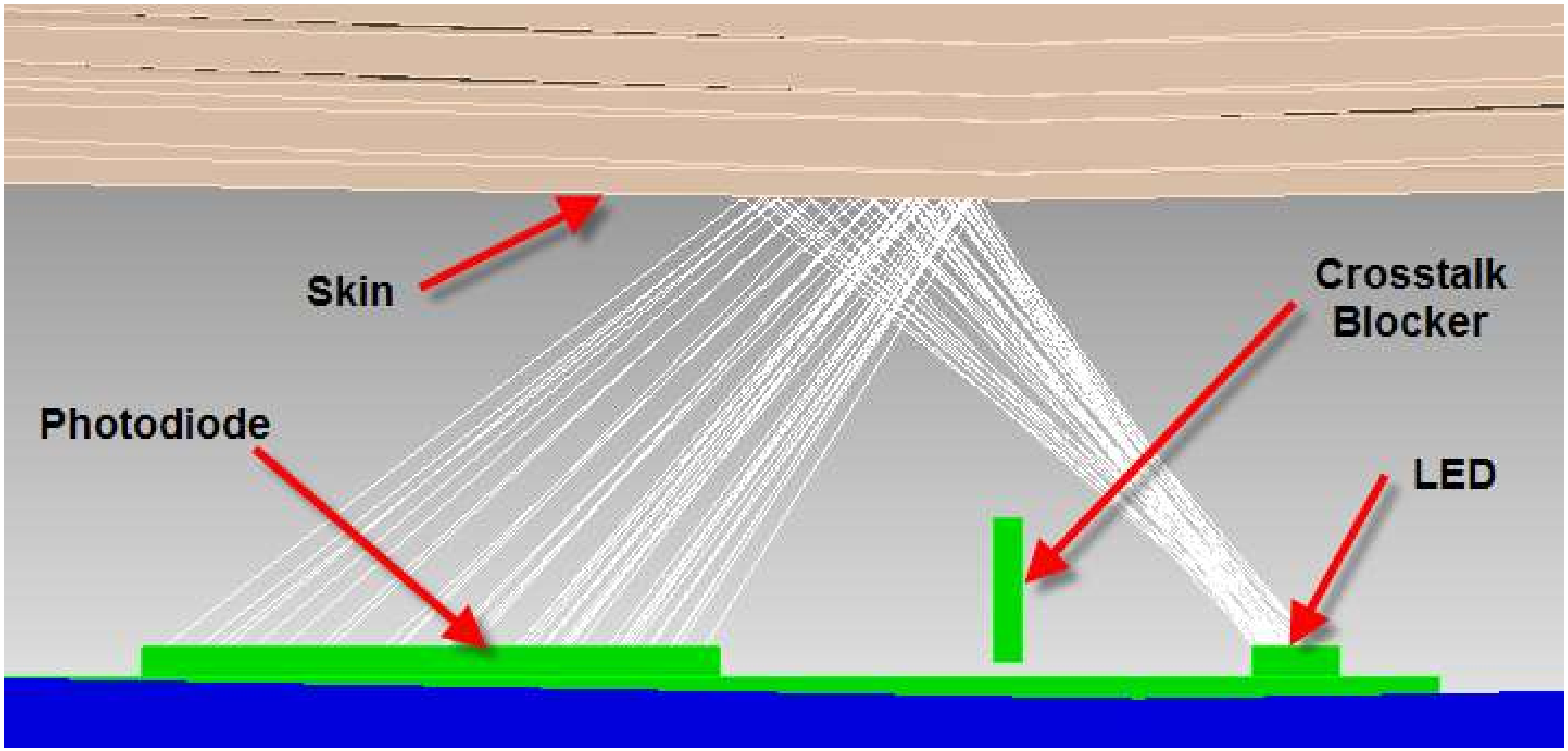
Reflective Pulse Oximeter Example – Stray Light Problem



Stray Light Path in the wrist wearable. The second path goes over the blocker and hits the epidermis layer of the skin and scatters directly to the photodiode without entering the wrist tissue. This is why it is important to have the wearable in contact with the skin so that the crosstalk blocker can do its job.

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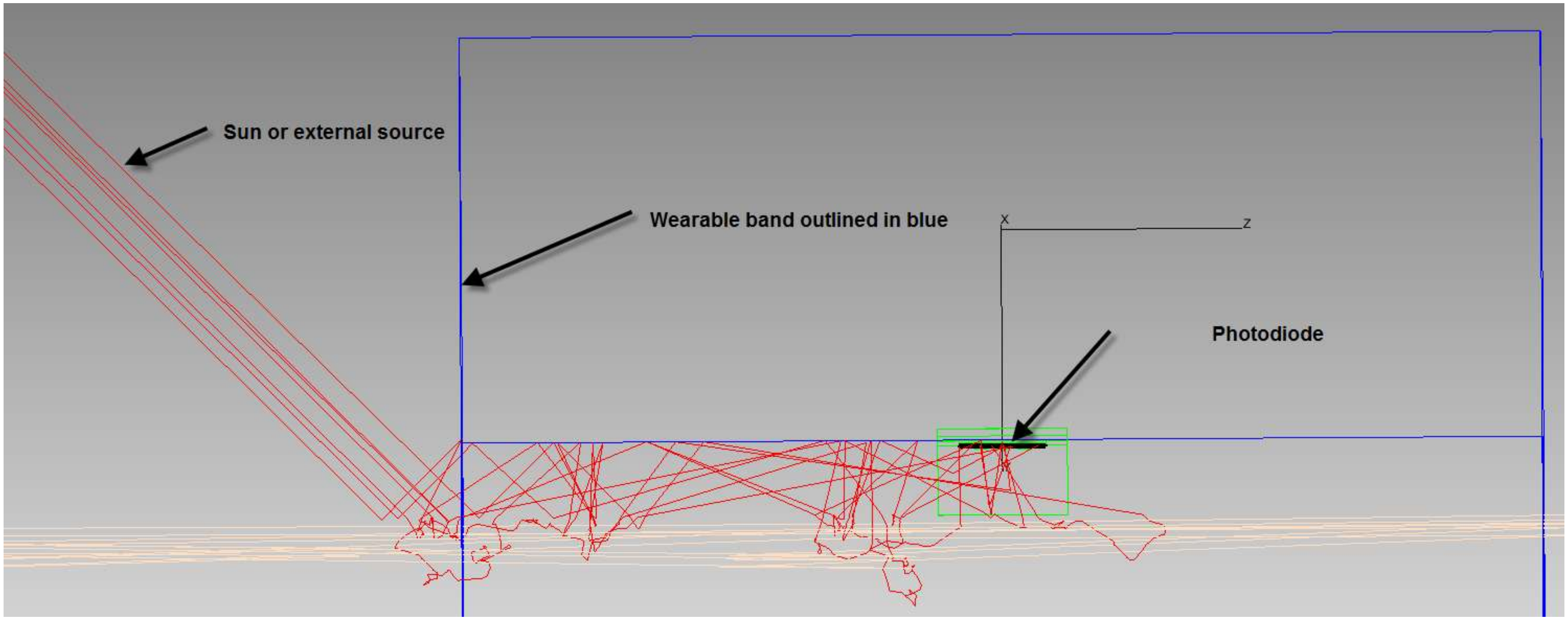
Reflective Pulse Oximeter Example – Stray Light Problem external source



Stray light path from an external source – depicted in this example is stray light from an external source, most likely the sun with the photodiode positioned on top of the wrist. This path will occur if the band is not snug against the wrist. Other possibilities of this problem could occur for other reasons, including slippage due to sweating, band material degradation over time due to skin conditions or holes in the band due to damage.

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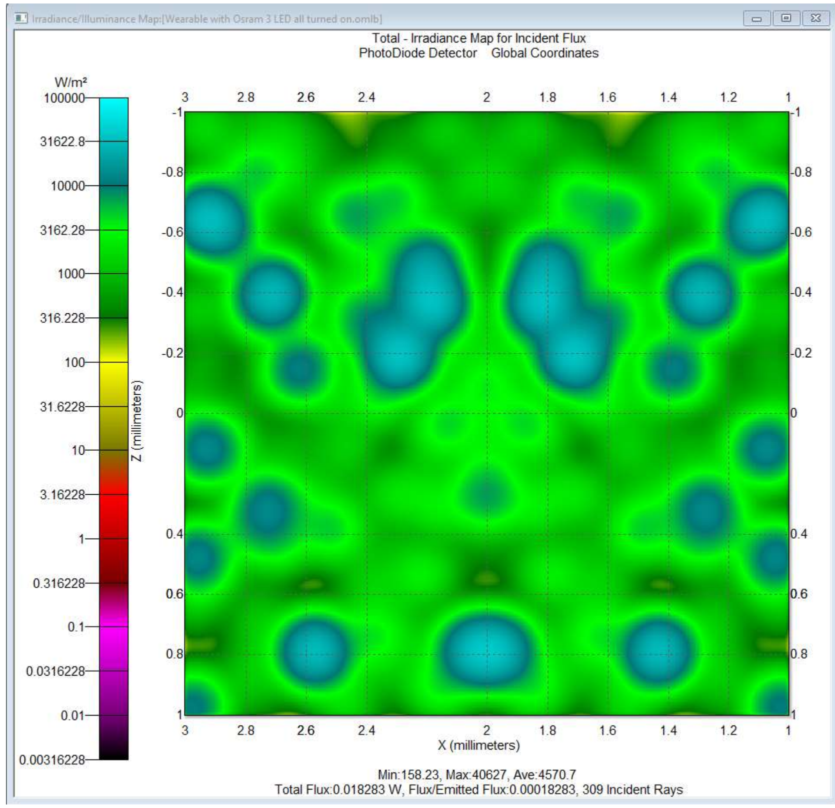
Reflective Pulse Oximeter Example – Sun Contribution as external source



The irradiance map for light entering the tissue from an external source like the sun in slide 25 reaching the photodiode is .018Watts. This stray light contribution is of the same magnitude as the Green, Red and IR LED contributions shown on slide 23. This external signal completely throws off the SpO_2 calculation causing the pulse oximeter to report completely invalid results.

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Benefits of Software Simulation

- It is well known that using simulation for virtual prototyping decreases the trial and error prototyping process in terms of time and money, reducing the need for multiple prototypes.
- Simulation software allows users to determine both throughput efficiencies through different materials and look at uniformity issues.
- Provides visualization by displaying rays in the design to ascertain light leaks and crosstalk that can't be seen by normal visual processes.
- Creates better product by giving the designer tools to see into the design and eliminate unwanted and problematic features, and provides optimization to create the best design though multiple iteration techniques.

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Conclusion

TracePro Analysis Features give the designer the tools to create better product

- Use Flux Reports to show absorption and throughput to any surface in the model to validate the throughput of the design.
- Use 3D Irradiance/Illuminance Maps to show power flow on or through an optical part or light guide.
- Use Visualized Ray Tracing to see light escaping, reflecting, transmitting or scattering when interacting with parts to verify paths.
- Use advanced path sorting to analyze and minimize crosstalk paths in the light guide.

References

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3 – https://www.maximintegrated.com/en/products/analog/sensors-and-sensor-interface/MAX30101.html – datasheet on the Maxim MAX3010x biosensor

4 – http://www.osram-os.com/Graphics/XPic5/00219346_0.pdf/SFH%207060,%20Lead%20(Pb)%20Free%20Product%20-%20RoHS%20Compliant.pdf – Osram BioMon Sensor SFH7060

5 - http://www.dcrainmaker.com/2015/09/tomtom-spark-first-impressions.html - First impressions on the Tom Tom Spark

6.http://incenter.medical.philips.com/doclib/enc/fetch/586262/586457/Understanding_Pulse_Oximetry.pdf%3Fnodeid%3D586458%26vernum%3D2 - Understanding Pulse Oximetry SpO2 Concepts – Philips Medical Systems

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Questions & Answers

Thank You!!

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Michael Gauvin
Vice President Sales & Marketing
sales@lambdares.com
+1 520-574-0150

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