IR UNIT & MEDICAL STANDARDS (IEC-60825-1 & ANSI Z136.1)

Ocular Response Analyzer:

The **Ocular Response Analyzer (ORA)** is a **non-contact** device used to measure **INTRAOCULAR PRESSURE (IOP)** and **BIOMECHANICAL PROPERTIES** of the cornea.

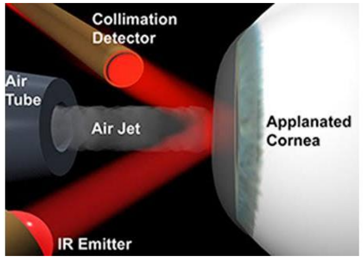
Unlike traditional tonometry methods (e.g., Goldmann applanation tonometry), which primarily measure IOP based on corneal flattening, the ORA offers a more comprehensive analysis by considering the **corneal biomechanics**.

How it Differs from an Air-puff Tonometer?

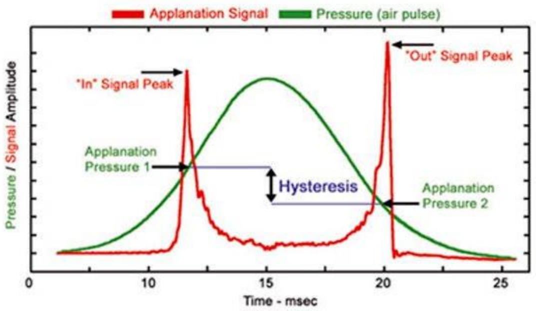
The **air-puff tonometer** measures IOP by using a puff of air to flatten (applanate) the cornea. The device detects the force or timing at which the cornea flattens, and from this, it calculates the intraocular pressure.It only uses **one applanation event** (the point where the cornea flattens due to the air puff) to calculate IOP.

The **ORA** uses an air puff to flatten the cornea, measuring two applanation events: one during inward movement and another as the cornea returns to its original shape. It calculates **corneal hysteresis (CH)—**the cornea's ability to absorb and dissipate energy—by analyzing the difference between these points. It also provides two IOP measurements: Goldmann-correlated IOP (IOPg) and corneal-compensated IOP (IOPcc).

ORA



Applanation



corneal hysteresis

Feature	Air-puff Tonometer	Ocular Response Analyzer (ORA)
Primary Measurement	IOP	IOP (IOPg and IOPcc) + Corneal Hysteresis
Applanation Events	Single Applanation	Dual Applanation (Inward & Outward)
Corneal Compensation	No	Yes (IOPcc accounts for corneal properties)
Biomechanical Measurement	No	Yes (Corneal Hysteresis - CH)
Use Cases	Routine IOP Screening	Glaucoma Management, Corneal Biomechanics
Corneal Abnormality Accuracy	Less accurate	More accurate due to IOPcc and CH
Non-Contact	Yes	Yes

We have choose the method of Ocular Response Analyzer ,which can be achieved in a Miniature model with High accuracy

So,

It requires a **Reliable IR unit ,**which should **adapt** with the **Medical Standards** because it will be directly used on the Eye and should be **highly faster** in terms of **Measurements.**

Why Infrared light?

In the Electromagnetic Spectrum range of Near Infrared (700 to 1400 nm) can **penetrate the cornea deeply and efficiently**, **minimizes light scattering**, provides **clear signal detection**, and **enhances patient comfort** by being **non-visible**. The use of NIR light allows for **accurate, non-invasive, and reliable measurements of IOP** and corneal biomechanics, such as corneal hysteresis (CH), making it an optimal choice for this device.

INFRARED-EMITTER:

Specs of IR emitter ,we have choose for Our **Tono_Lite:**

Feature	IR-LED
Wavelength	860 nm
Radiant Intensity	500 mW/sr
Beam Angle	6 degree
Rise & Fall Time	12ns
Mounting Style	Through Hole

*Fastest IR Emitter (12ns)

* 860nm is ideally used in Air-puff tonometer and ORA ,due to better reflection by cornea.

*IR needs to focus on the center of the cornea (11mm) to get the accurate Results ,So the IR beam we have choose (6 deg) covers 2.17<11mm ,which can accurately Emit the IR wave to the center of the cornea.

How it Meets the **Medical Standards** Guidelines ?

Irradiance :

Irradiance refers to the power of electromagnetic radiation (like light) per unit area incident on a surface, typically measured in watts per square meter (W/m^2). In the context of an **IR (infrared) emitter**, irradiance measures how much infrared energy (in terms of power) hits a specific area.

Irradiance (E) Calculation for the specified IR emitter:

E=I/d^2

Where:

E = irradiance (mW/cm^2)

I = radiant intensity (mW/sr) (500mW/sr)

d = distance from the emitter in centimeters (cm) (d=2.5)

So,

Calculated **E= 84.22mW/cm^2.**

Medical Standard (IEC-60825-1 & ANSI Z136.1) :

*IEC-60825-1 & ANSI Z136.1 :

It is the Medical Guideline should be followed to ensure eye safety when the exposure Light is IR laser (narrow beam)

Maximum Exposure Time (t) =(Irradiance/(MPE coefficient×C4×C6))^1.33

Irradiance = **84.22mW/cm^2**

MPE coefficient = 2.7×10^4

C6=1

C4=3.16 (above all ideal for Wavelength of 860nm from the guidelines)

By substituting all the values,

Finally ,MPE (t) = 42 ms

Time taken by the Total applanation and rebound time is 20 to 25 ms
(The Maximum Permissible Exposure time is **more than enough** for our application)

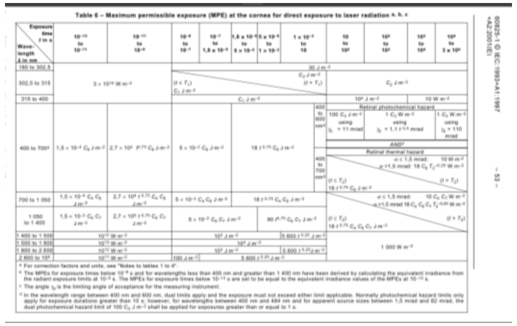
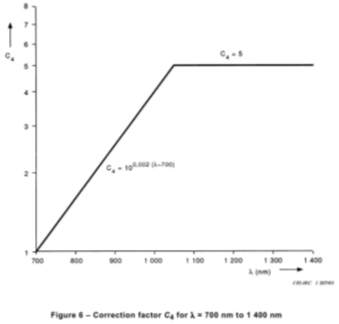


Table 6 – Maximum permissible exposure (MPE) at the cornea for direct exposure to laser radiation

MPE



Correction Factor

Finally ,We can conclude that ,the IR Emitter is **the best** fit our application.
<if anything after evaluation doesn't fit with **medical conditions** ,it will overhauled>

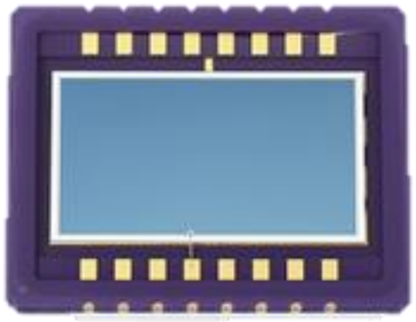
*Before the air-puff Reflected output from the Cornea's convex shape is **broader**.
*After the puff from the puff unit ,cornea applanates and reflects the emitted IR waves **narrow.**

*The reflected IR wave will be **2-5% (**1.6868-4.217 mW/cm^2) **in the emitted signal ,**we can significantly detect the reflected wave from when the **emitter and sensor are 30-45 degree** placed to the eye's central part
*To detect the reflected low power IR wave ,we require a robust sensor

Photo-Diode:

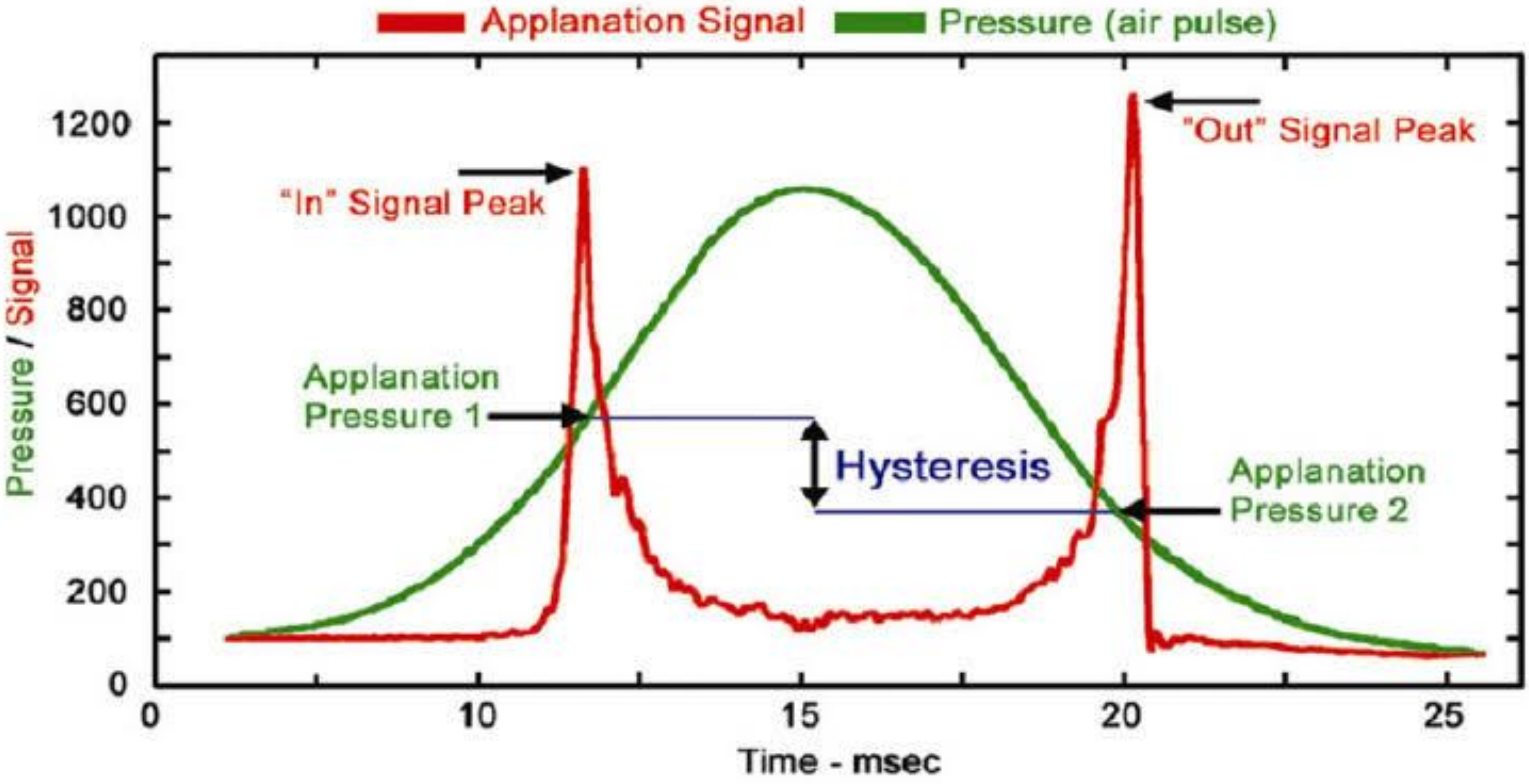
Feature	Photodiode
Wavelength	320 to 1100 nm
Type	Si-PIN
Photosensitivity	0.72 A/W
Response Time	0.5ns
Mounting Style	SMT
Dark-Current	10000 pA
Photo-sense Area	11 × 6 mm
Least Irradiance Detection	0.0417 mW/cm²

Ta=25 ℃, Typ., Photosensitivity: λ=λp, Dark current: V_R==10 V, Cutoff frequency: V_R=10 V, Terminal capacitance: V_R=10 V, f=1 MHz, Noise equivalent power: V_R=10 V, λ=λp, unless otherwise noted



Due to its **High Sensitive and Rapid Response Time** ,it will be ideal for our application

Finally with **the corneal hysteresis analysis and CCT** value ,Controller unit determines the IOP without any miscalculation.



corneal hysteresis