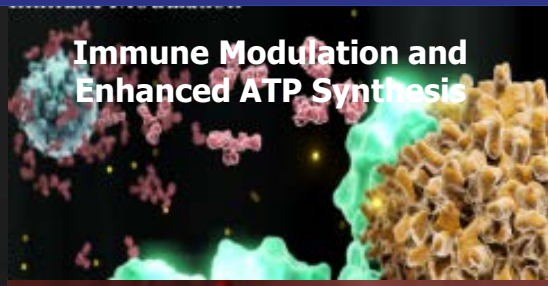
UVL Rx THERAPEUTICS

An Introduction to UVL Rx

Expanding the Therapeutic Boundaries of Light Therapy

UVLRx™ THERAPEUTICS

One device.
Three wavelengths.
No removal of blood.



Therapeutic Innovation.

UVLRx THERAPEUTICS

UVLRx Therapeutics

- **US-based Medical Device Manufacturer**
  - Manufactured in USA
- **UVLRx Station™**
  - Direct-to-blood (Intravenous) delivery system
  - Compounded, multi-wavelength light protocol
  - Based on established principles of photochemistry
  - Modulates cell biochemistry and physiology to achieve desired clinical responses
  - Ruled as a Non-significant Risk Device

UVLRx™ THERAPEUTICS

Light Therapy

- **In use for over 100 years to treat a variety of diseases**
  - Nobel prize in Medicine in 1903 for treating Lupus
  - 100% Success Rate
  - First patented UV device - 1928
  - Used in American Hospitals in 1940s
  - Treated bacterial and viral infections (Polio), Lupus, TB, Hepatitis, Pneumonia
- **Supplanted in the late 1950's by inexpensive and effective antibiotics – prior to drug resistance development**
- **UV device FDA cleared in 1987 for lymphoma (cancer)**
- **Today UV is used to sterilize surgical instruments and entire surgical suites to eliminate MRSA and even Ebola virus**

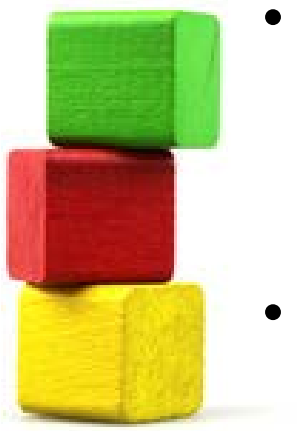
UVLRx THERAPEUTICS

UVLRx Differences

- **The UVLRx Station™ is the FIRST intravascular light therapy system**
- **The first and only compounded scientific treatment protocol**
  - Comprised of multiple therapeutic wavelengths
- **Integrates into the standard of care for multiple conditions and environments**
- **UVLRx Therapeutics is committed to evidence-based medicine**
  - Device design based on dozens of studies on the clinical efficacy of specific wavelengths employed
  - Completing studies elucidating safety and clinical effectiveness of device
  - Focused on regulatory clearances by indication for each geography

UVLRx THERAPEUTICS

The Building Blocks of UVLRx Therapy



- **Pathogen Deactivation**
  - Damaging and destroying viruses, bacteria and fungus in the blood.
  - Active and prophylactic infection control
- **Inflammation and Immune System Modulation**
  - Reducing pro-inflammatory cytokines systemically reducing risk and contributory factors for a variety of conditions
  - Boost both active and innate immune system to manage existing infection while preventing or inhibiting future development
- **Enhanced ATP Synthesis**
  - Boost cellular-level energy stores for systemic energy, tissue regeneration and infection defense
- **Red Blood Cell Support and Increased Oxygen Delivery**
  - Improve RBC elasticity and decrease blood viscosity
  - Improve oxygen affinity (attraction and rapid exchange of gas)

UVLRx™ THERAPEUTICS

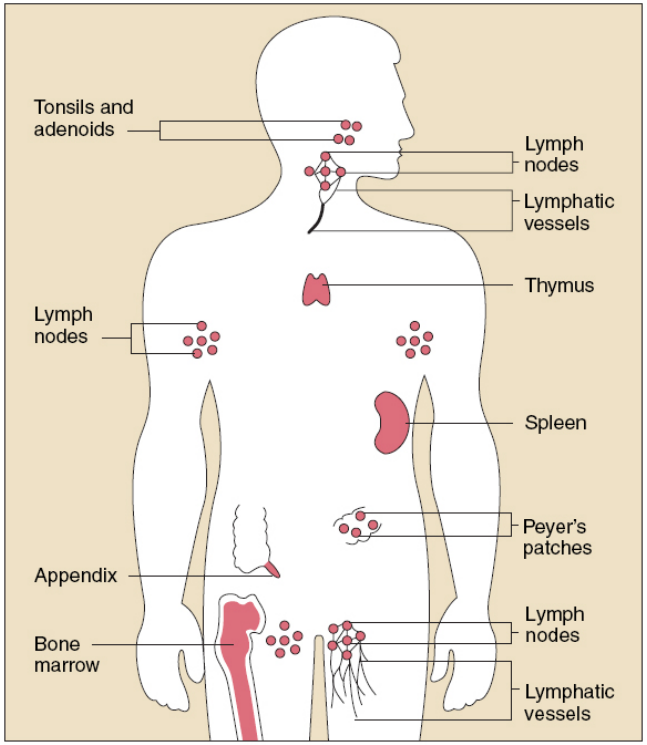
Pathogen Deactivation

- **Interrupt cell DNA Sequence**
- **Inhibit ability to replicate**
- **Inhibit ability to bind**
- **Compromise cell structure and wall**
- **Allow body's own immune system to destroy and remove pathogens**
- **Facilitate development of antibodies**

UVLRx THERAPEUTICS

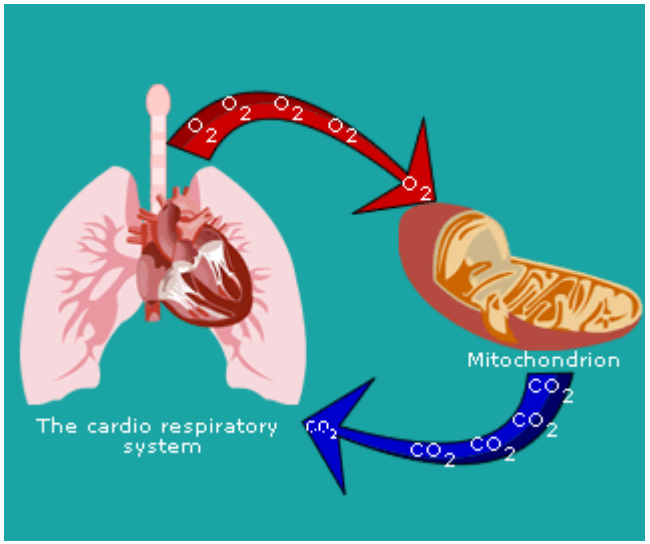
Immune System Modulation

- **Modulate immune system response to viruses and other pathogens**
- **Reduce inflammation**
  - Modulate pro-inflammatory cytokines
- **Inhibit virus and tumor propagation**
- **Increase mitochondrial activity**
  - Increase in ATP provided more energy at the cellular level to fight infection
  - Promote cellular differentiation and cell repair
  - Improve inter-cellular communication to response to pathogens more effectively and rapidly



Increased Oxygen Delivery

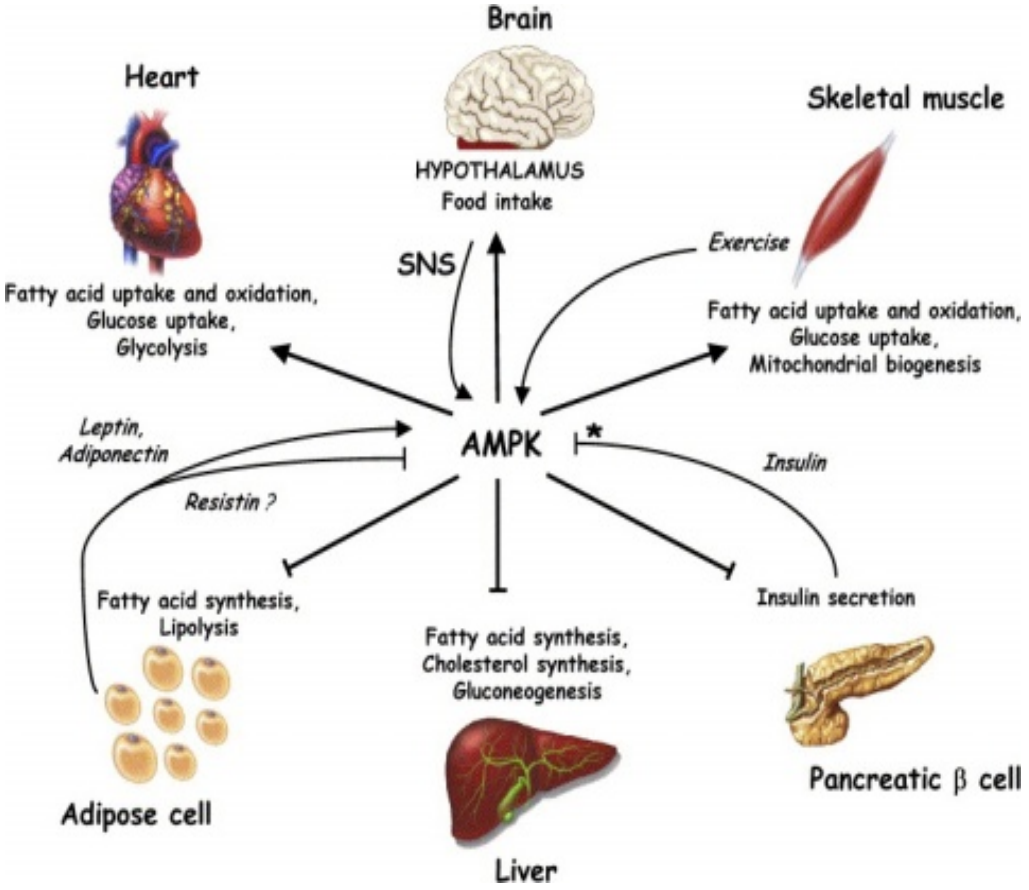
- **Improve oxygen affinity**
  - Increase attraction of oxygen to hemoglobin
- **Increase hemoglobin in red blood cells**
  - Improve ability to carry more oxygen
- **Decrease in lactic acid**
- **Reduce blood viscosity**
- **Improve blood flow**



UVLRx THERAPEUTICS

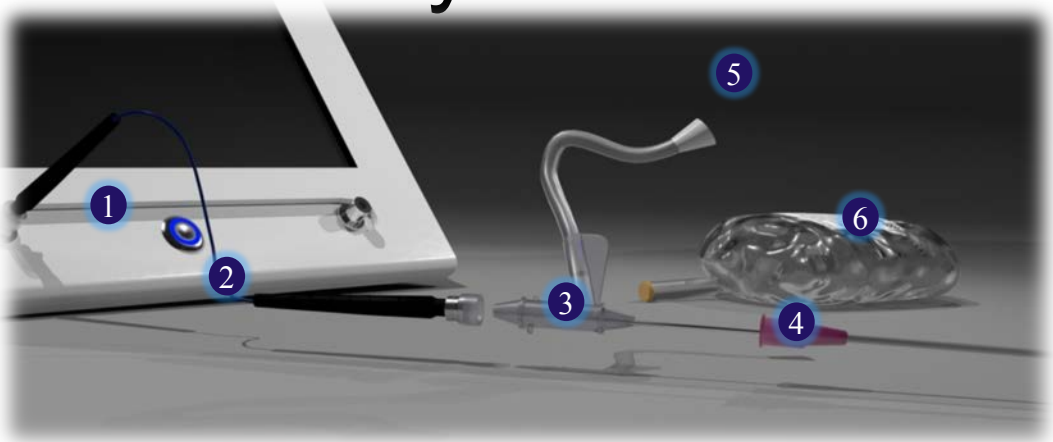
The Impact of ATP

- Adenosine Triphosphate (ATP)
- The role and impact of ATP is far reaching
- Provides the intercellular energy to fuel metabolic processes
- Used as a substrate for signal transduction



UVLRx™ THERAPEUTICS

UVLRx Treatment System™



1. **UVLRx Station™** – Manages treatment and accurate dosing
2. **Patient Cable –** Delivers light from the UVLrx Station to the DLA
3. **UVLRx Dry Light Adapter™ (DLA) –** Delivers light into the bloodstream
4. **20-gauge 1.0" Peripheral Intravenous Catheter –** Provides venous access
5. **The Saline Port -** Allows for the concurrent flow of IV solutions
6. **Intravenous solution –** Eliminates back flush and distal coagulation

UVLRx THERAPEUTICS

UVLRx Station™

- **Automated treatment management alleviates the need for continuous supervision during treatment**
  - Single setup
- **LED light source delivers a multi-wavelength therapy protocol**
  - No transmission of heat
- **Calibration of each wavelength before each treatment assures accurate dosing**

UVLRx THERAPEUTICS

UVLRx Dry Light Adapter™

- **Sterile, consistent, therapeutic light transmission**
- **Inserted into a standard, 20 gauge IV catheter**
- **Integrated saline drip manages backup and coagulation**

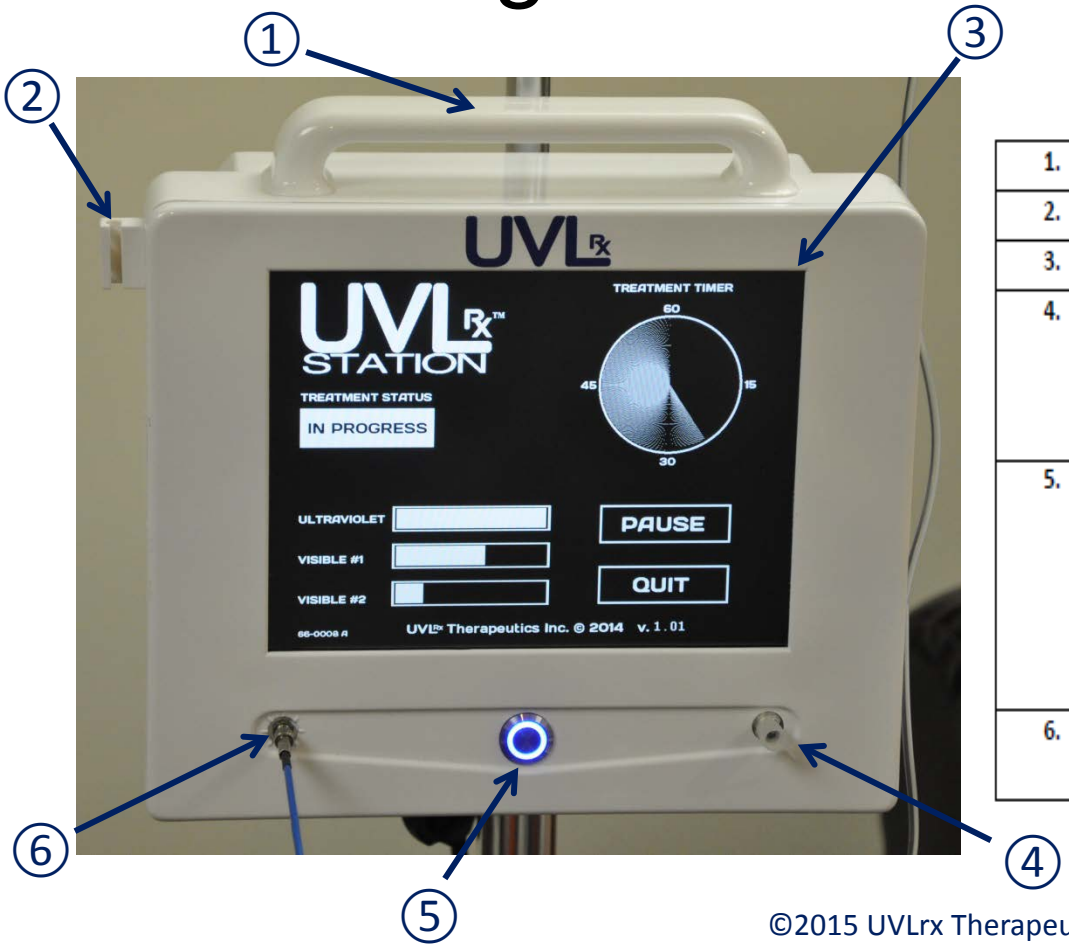
UVLRx THERAPEUTICS

Patient Experience

- **Treatment Cycle is 60 minutes**
- **Single Catheter insertion**
- **Treats 100% of the blood during cycle**
- **Integrates into the standard of care for clinics, ICU, PACU, ED**

UVLRx THERAPEUTICS

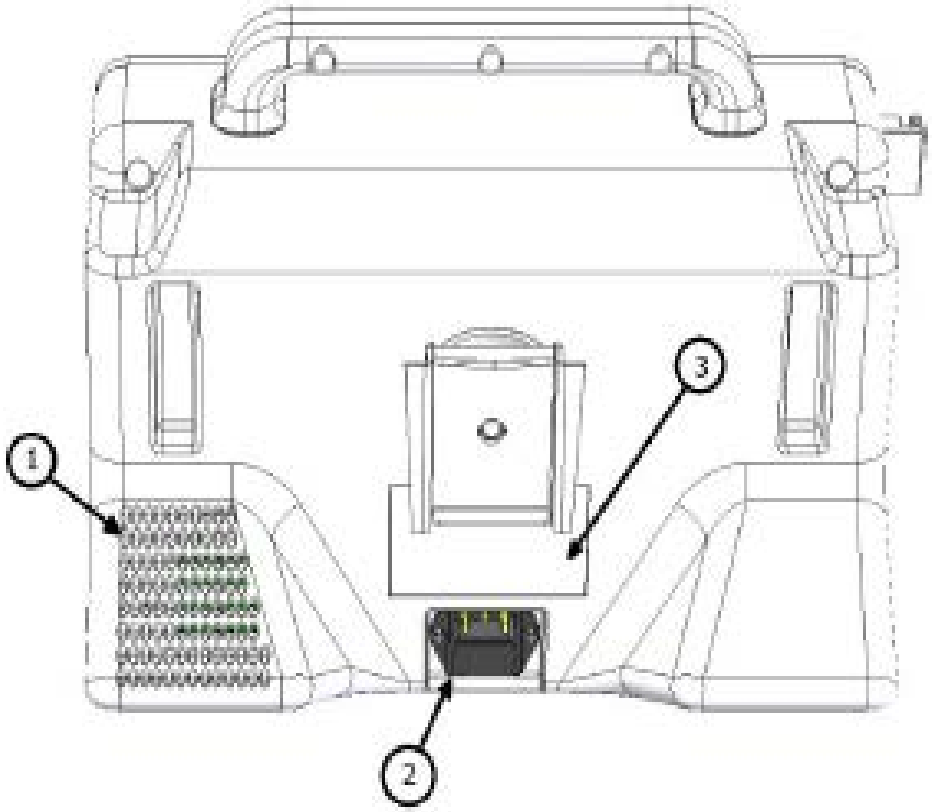
Introducing the UVLRx Station™ - Front



1. Handle	Allow user to move the device
2. Patient Cable Holder	Holds fiber optic cable when not in use
3. Touch Screen Display	Provides graphical user interface
4. Calibration Port	The distal end of the Patient Cable (with the DLA adapter and Slip Lock Ring) connects to this port for calibration prior to each treatment. Ensure Integrated dust-cap in place between calibrations.
5. Blue Ring-Lit Power Switch	Provides user with means to power device on or off. "Blue" ring-lit module provides visual of device's powered status ("breathing" = AC mains connected; continuously lit = device is ON). One press turns the device ON. Press and hold the button for two seconds to turn the device OFF.
6. Emission Port	UVLrx Multi-Wavelength Protocol™ emitted from this port. Patient Cable normally connected to this port.

UVLRx™ THERAPEUTICS

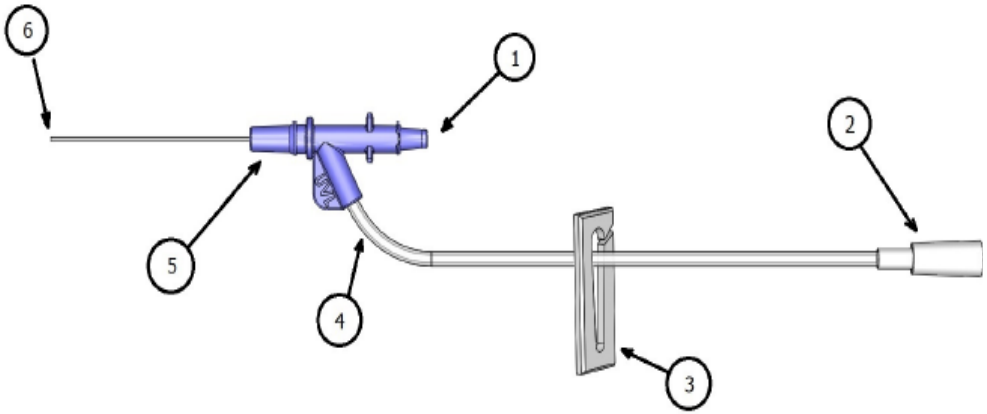
Introducing the UVLRx™ Station™ - Back



1. Exhaust Fan Vent	Vents air from within device. Leave at least 2" between this side and an opposing surface (e.g. wall)
2. Power Entry Module	Connect to AC mains with IEC compatible power cord.
3. Device Label	Supplies device specific information. Additional Investigational Device label can be found on bottom of device.

UVLRx™ THERAPEUTICS

Device Introduction (Dry Light Adapter™)



1. Patient Cable Optical Interface	This end slides into the tapered adapter of the Patient Cable, and is secured there with a ¼ turn of the Patient Cable's slip lock ring.
2. Luer Connection to Saline Drip	Connection for standard saline drip.
3. Slide Clamp	The Slide Clamp prevents ingress of fluids after the DLA is primed with saline.
4. Saline Entry Port	Saline from the saline drip enters the body of the DLA here, flows into DLA, and out alongside of the optical guide and into the patient.
5. Tapered Nozzle	Provides secure, leak-free press fit connection to standard 20ga x 1" catheter.
6. Optical Guide	This component delivers optical energy received from the Patient Cable down into the existing catheter. The Optical Guide is contained within a hypodermic stainless steel guide, and does not extend beyond the catheter lumen, nor into the patient's body.

UVLRx THERAPEUTICS

UVLRx Patient Treatment Kit

2x2 Gauge Pad

Cotton Ball and Tape Roll

IPA Preps x2

Tourniquet

Sterile-packaged UVLrx Dry Light Adapter™

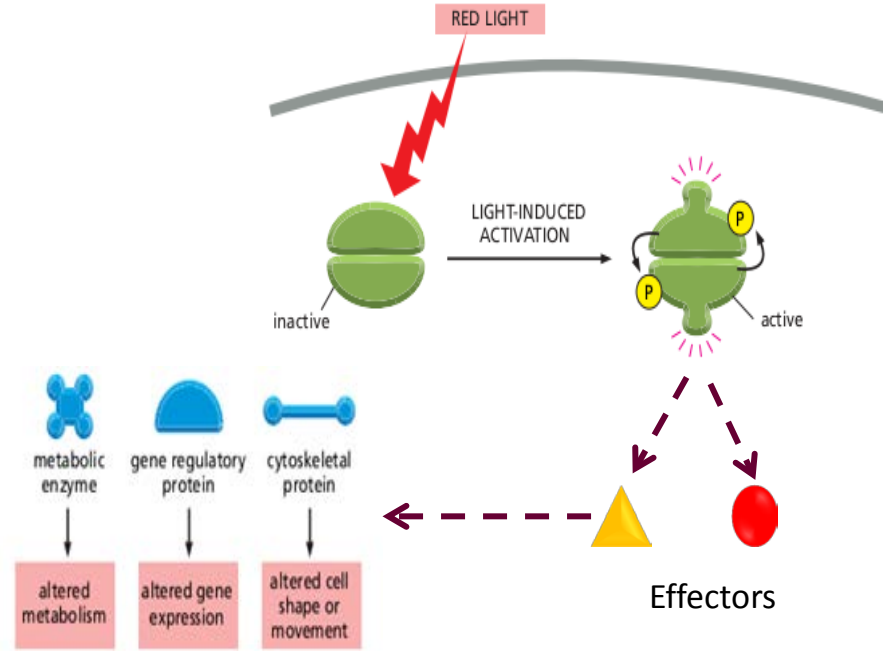
IV Catheter 20 Gauge x 1”

Transparent Film Site Shield

UVLRx THERAPEUTICS

Light Mechanism

- Specific molecules respond following the absorption of specific colors of light (known as photoreceptors)
- Light absorption affects their structure which affects their overall chemical behavior
- All enzymes and/or proteins associated with that structure are affected
- This cascade event can ripple across an entire cell

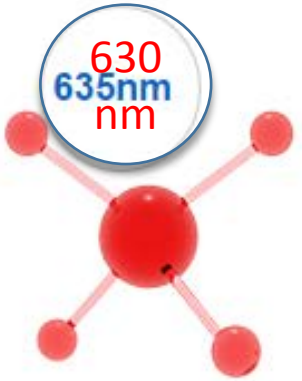


Change cell behavior and function

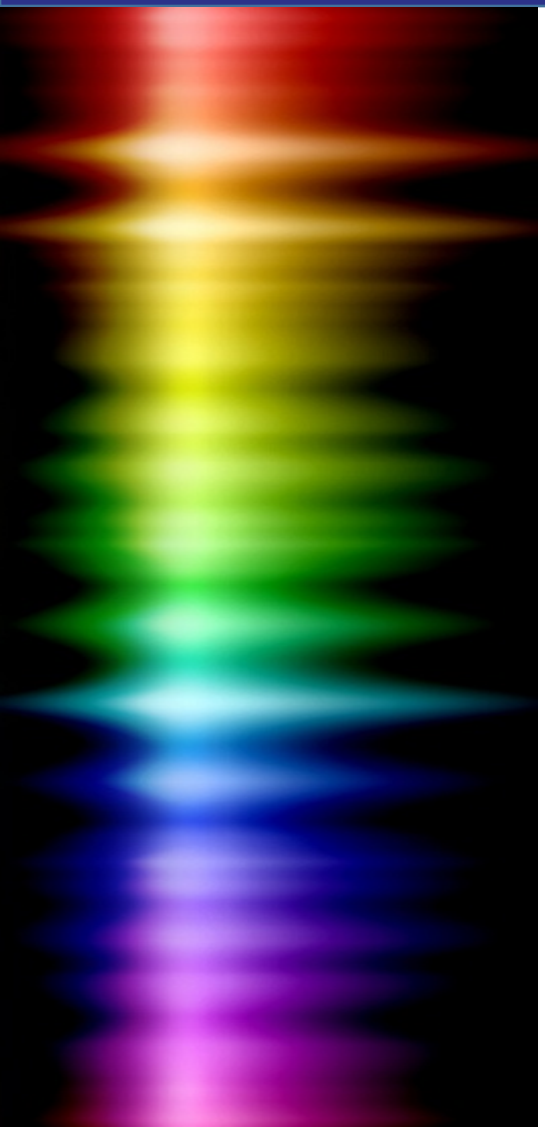
UVLRx THERAPEUTICS

Light Therapy

- The UVLRx Station™ administers three discrete wavelengths
  - Each serve as the active ingredients in the UVLrx therapy
  - Each wavelength targets a specific photoreceptor to affect a specific sequence of biochemical cascades.
  - Concurrent delivery of each wavelength provides a comprehensive clinical response



UVLRx™ THERAPEUTICS



Red – 630nm

- Increases cellular energy (ATP production)
- Reduces pro-inflammatory cytokine production
- Stimulates immune cell function, slowing or stopping infection

Green – 535 nm

- Improves the function and behavior of the red blood cell
- Improves red blood cell elasticity to deliver oxygen to tissue
- Improves hemodynamics, with reduced blood viscosity
- Activates reparative and stabilizing pathways.

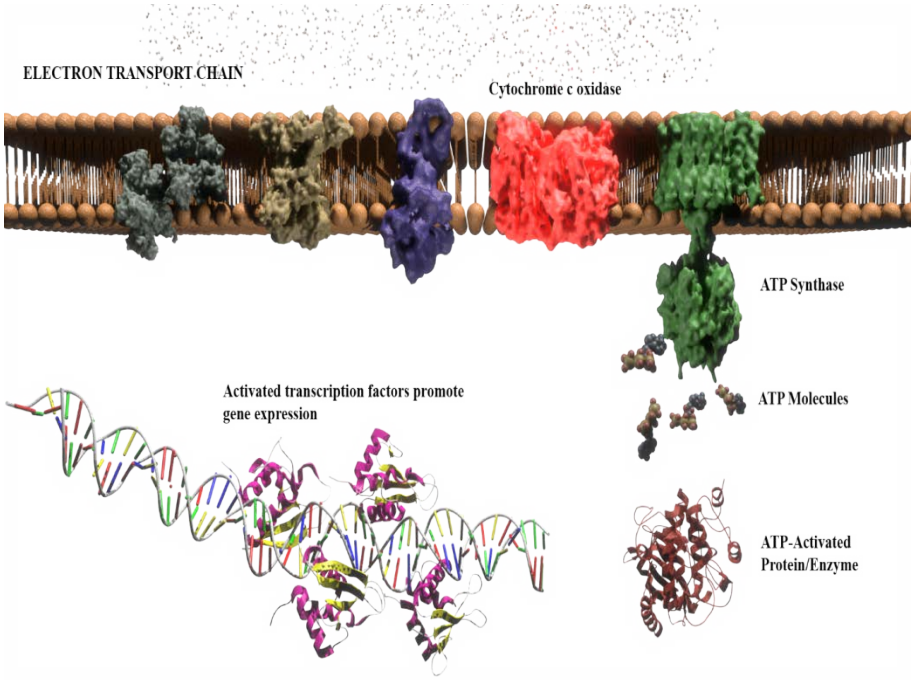
UVA – 365 nm

- Well-known and established antimicrobial agent
- Produces sub-lethal pathogen damage to stop replication and increases susceptibility to immune degradation

UVLRx THERAPEUTICS

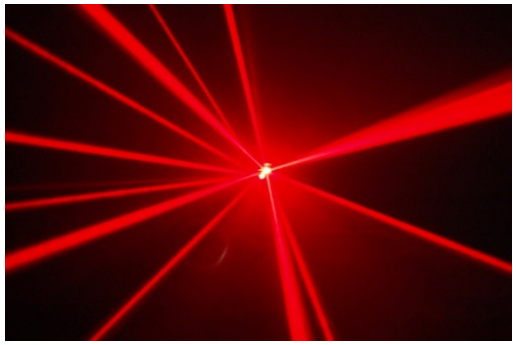
Light Therapy (Red-630 nm)

- **630 nm wavelength represents one of the most studied therapeutic wavelengths**
- **630 nm has been shown to stimulate the enzyme cytochrome c oxidase**
  - serves an important role in producing adenosine triphosphate (ATP)
- **ATP is an important energy molecule that helps many cellular reactions proceed**
  - More energy in the cell helps to maintain or drive proper function and behavior
  - Especially when the cell is stressed, nutritionally starved, or damaged

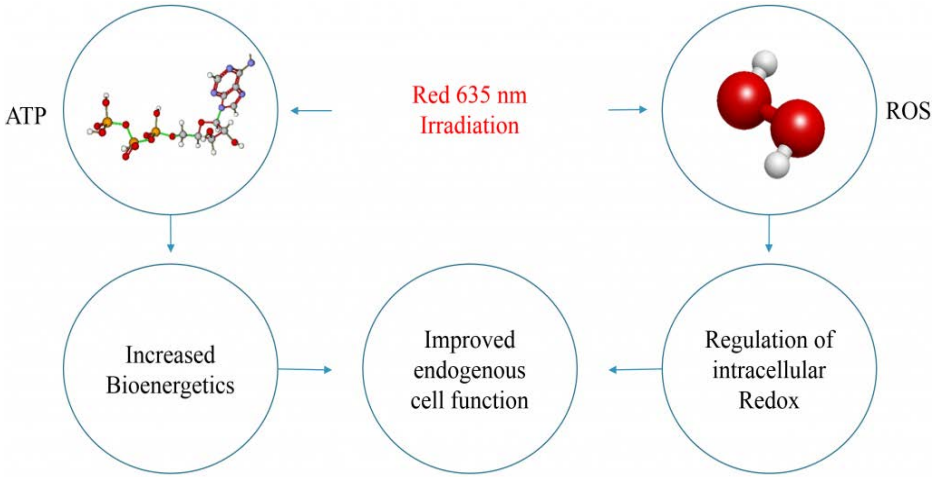


UVLRx THERAPEUTICS

Light Therapy (Red-630 nm)

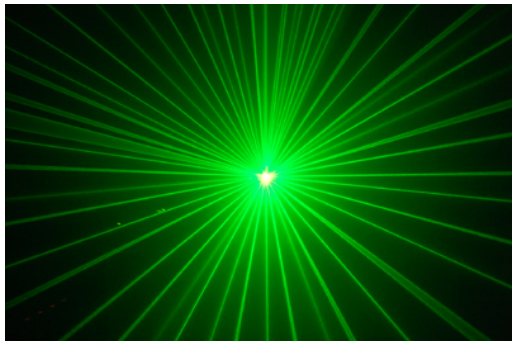


- **Improve immune function while reducing pro-inflammatory cytokines**
  - Pro-inflammatory cytokines can cause vasoconstriction and rapid rise in body temperature
- **Increase immune cell's ability to engulf and destroy pathogens by producing reactive oxygen species (ROS)**
  - Advances destruction of pathogens
  - Builds pathogen-specific antibodies



UVLRx THERAPEUTICS

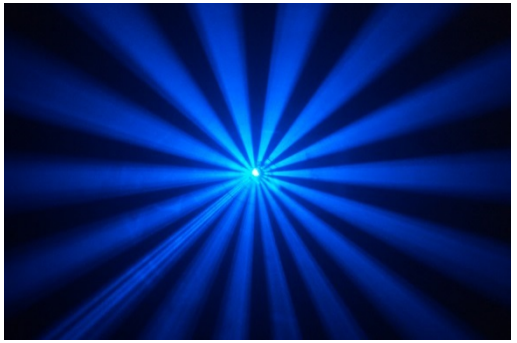
Light Therapy(Green-535nm)



- **Green (535 nm) wavelength has been shown to induce profound effects on blood components and hemodynamics, activating reparative and stabilizing pathways.**
  - Platelet activation with gradual loss of natural platelet reactivity and ability to respond to activating agents
  - Positive effect on Sodium/Potassium Pump, which helps to regulate intra- and extra-cellular cation homeostasis
  - Improve red blood cell elastic properties, improving rheological function
- **Stimulation of the red blood cells help improve the function of the red blood cell**
  - important to help preserve the key function of this cell, gas exchange

UVLRx™ THERAPEUTICS

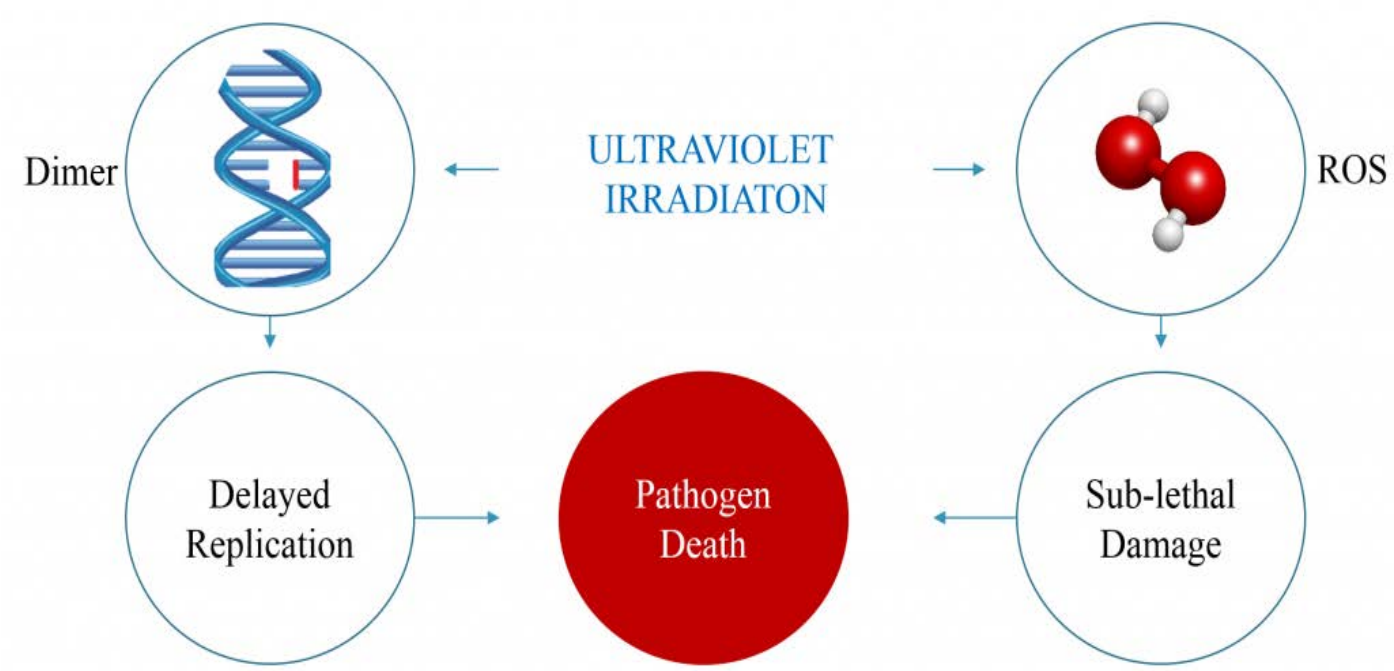
Light Therapy (UVA-365)



- **UVA is a well established antimicrobial agent**
- **Greatly reduced risk to human cells**
- **Pathogens have a higher susceptibility to UVA irradiation**
- **The antimicrobial effects of UVA result from:**
  - Increased production of toxic reactive oxygen species (ROS)
  - Delayed pathogen replication
  - Pyrimidine dimer formation
- **UVA exposure primarily promotes sub-lethal effects, which stop replication and increase the pathogen's susceptibility to immune degradation**
- **Pathogen damage permits the release of antigens in which the immune system can build highly-specific antibodies to the pathogen strain**

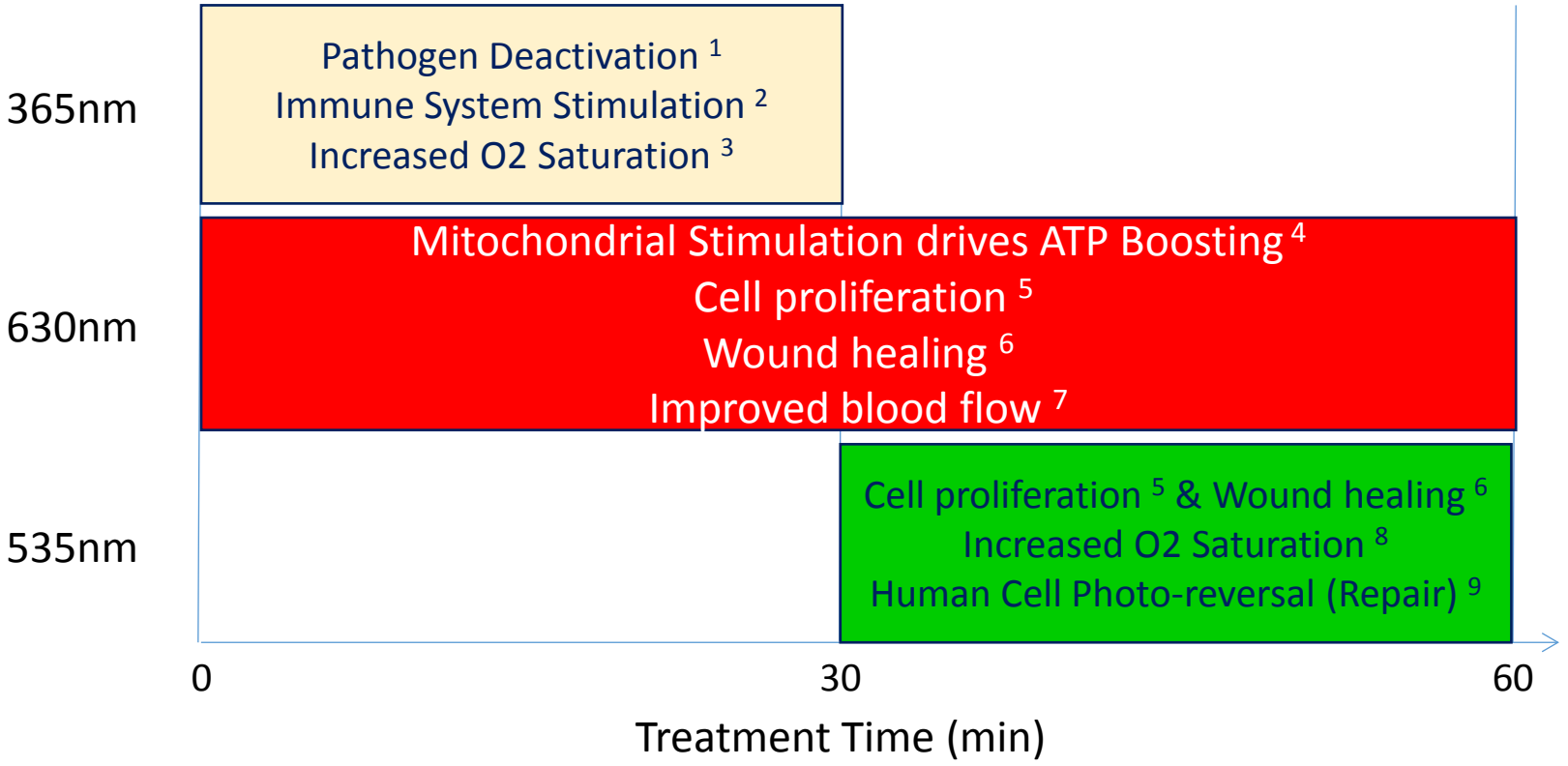
UVLRx THERAPEUTICS

Light Therapy (UVA-365)



UVLRx THERAPEUTICS

Treatment Protocol



UVLRx™ THERAPEUTICS

Patient Safety

- **Non-significant risk classification**
- **FDA Class II medical device**
- **Uses standard IV catheter**
- **Long history of safe light therapy treatment**
- **Simple saline drip during treatment hydrates patient and maximizes light penetration**
- **UV light introduced is less than 1 minute of direct sunlight exposure on the skin**

FDA Regulation

Investigational Device Exemption (IDE) - 21CFR Part 812

- **An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data**
  - Clinical studies with devices of significant risk must be approved by FDA and by an Institutional Review Board (IRB) before the study can begin.
  - Studies with devices of non-significant risk must be approved by the IRB only before the study can begin.

FDA Regulation

21CFR Part 812.7 Prohibition of promotion and other practices.

- **A sponsor, investigator, or any person acting for or on behalf of a sponsor or investigator shall not:**
  - (b) Commercialize an investigational device by charging the subjects or investigators for a device a price larger than that necessary to recover costs of manufacture, research, development, and handling
- **Prices set are to recuperate costs therefore, the research price represents a substantially reduced price compared with the commercialization price**

UVLRx THERAPEUTICS

Clinical Safety IRB Study

- **Independent Review Board (IRB)**
  - Salus IRB, Austin, TX
- **Official Study Focus on device safety**
  - Secondary IRBs to be filed for specific conditions with unique indicators and endpoints
- **Target**
  - 2000 patient study
  - 30-day evaluation period
- **Special IRB packages for study participants**

UVLRx THERAPEUTICS

Target Regulatory Approvals

- **FDA Clearance**
  - IRB Studies approved and kicked off Summer 2014
  - Target approval by Q3, 2015
- **CE Mark expected in Q2 – 2015**
  - Initial trial complete, March 2015
- **ISO 13485**
  - Process documented
  - Compliance building blocks in place
  - Expected approval, April 2015
- **Device Compliance**
  - ISO 9001:2000
  - ISO 60825-1 – Light Safety
  - IEC 60601-1-1 Safety
  - FDA Good Manufacturing Practices

UVLRx™ THERAPEUTICS

Financing Options

- **Multiple financing partners**
- **Simple, single-page application process**
- **Rapid submission and response (1 hour)**
- **Self-funding program with $0 down and 90-day deferred payment options (Physicians resident in the US-Only)**
- **Detailed Section 179 tax credit summary**

UVL Rx™ THERAPEUTICS

Thank You.

For Questions and to place orders please contact us at:

Paul@uvlrx.com **www.UVLrx.com** **(844)885-7979**

UVLRx™ THERAPEUTICS

Company History

- **2010**
  - Mike Harter, nationally known marketing executive and philanthropist was looking to align work with his humanitarian heart when he first heard of the UBI concept
  - Spent a year to research UBI therapy, improvements to treatment administration, mechanisms of action, latest technologies incorporated into a single device
- **2012**
  - Established company to engineer the UVLrx Station
  - Developed innovations in delivery incorporating the best of the latest technical advancements in electronics, optics, and software to create the UVLrx Station and DLA

UVLRx THERAPEUTICS

Company History

- **2013**
  - Established Corporate HQ in Santa Barbara, CA
  - Partnered with Rowland Hanson to build organization around the new device
  - Refined design and build parameters and process
- **2014**
  - Launched clinical trials of UVLRx Station
  - Established global distribution
  - Complete international patents and trademarks
  - Established Device Manufacturing in Tampa, FL

UVLRx™ THERAPEUTICS

References

Pathogen Deactivation

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Immune System Stimulation

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Increased O2 Saturation

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UVLRx™ THERAPEUTICS

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