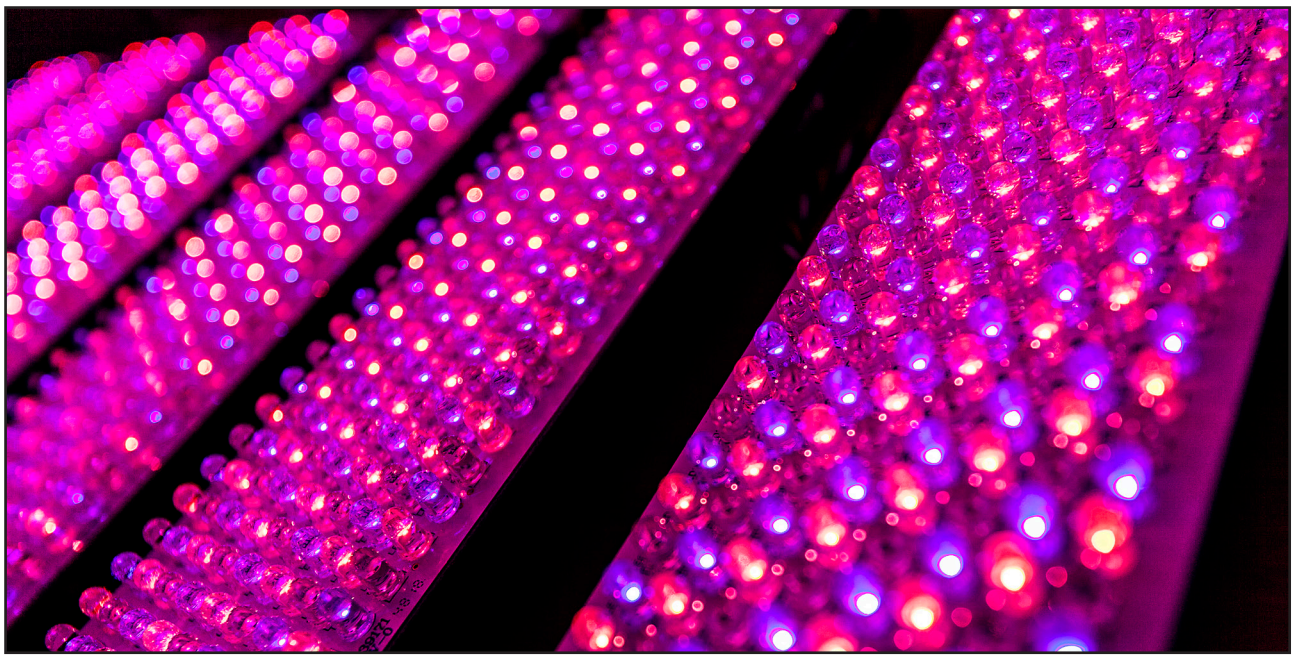

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A GOOD LED LIGHT OR NOT, CE IS THE QUESTION?

Dale Needham, Managing Director of Aesthetic Technology Ltd looks at the science behind light-emitting diodes or LEDs

Light-emitting diodes (LEDs) are commonly found in many different market sectors and industries, from general illumination in homes, offices and warehouses to types of signalling such as car indicator lights, and more recently within car headlights. In the medical and aesthetic marketplace, the use of LEDs has also become commonplace for LED phototherapy.

What is an LED?

An LED is a small, light-emitting diode that emits light when an electric current is passed through it. Electrons in the semiconductor recombine with electron holes resulting in the release of energy as a photon.[1] At the time of manufacture, and when in combination with varying materials, the light which is emitted can be fine-tuned at source to emit as a pre-selected peak wavelength. This results in a defined spectrum of light being emitted.

This spectrum can be refined at source with the addition of further nanomaterials to define the shape of the light spectrum. Achieving smaller peak wavelength tolerances are a result of good material choices at the point of manufacture and most importantly, something referred to as 'binning'.

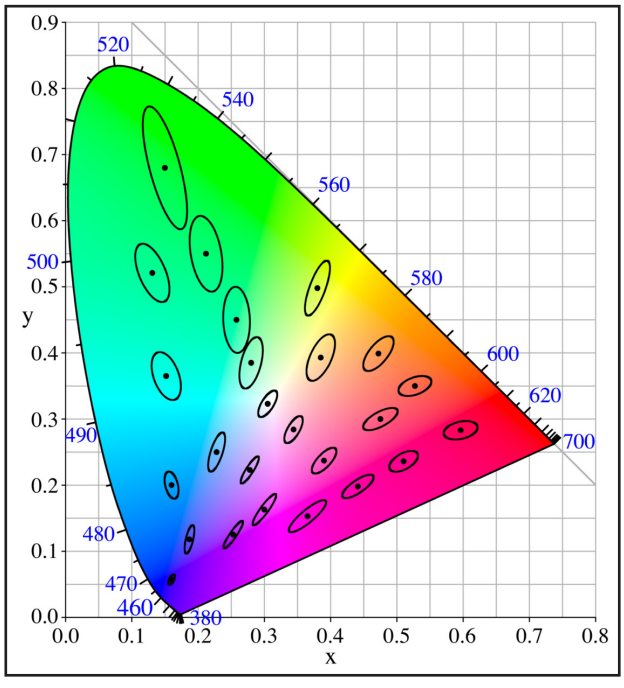
Typical peak wavelength tolerances are +/-5nm, better quality LEDs will be further defined to within a +/-2nm tolerance.

All LEDs are subject to a process known as 'binning'; this process has been refined over many years and nowadays typical manufacturers of LED components will provide the purchaser with two options - traditional binning or binning via MacAdam Ellipses.

Philips Lighting refers to a MacAdam Ellipse as "an elliptical region on the CIE chromaticity diagram that contains all the colours that are indistinguishable to the average human eye, from the colour at the centre of the ellipse".[2]

The diagram below demonstrates the 25 varying MacAdam Ellipses on the 1931 CIE chromaticity diagram:

Diagram 1: 1931 CIE diagram with standard 25 MacAdam Ellipses.[8]



In theory, binning via MacAdam Ellipses lends itself in particular to general white light illumination devices as its primary focus is colour quality and definition.

Ellipses are typically found to be ranked in size by a 3, 5 or 7-step MacAdam Ellipses. The larger the step, the greater area of the chromaticity diagram the ellipse covers, this, therefore, results in an increased variability of emitted colour in one 'bin'.[3]

An example of MacAdam Ellipse binning (to the right) for "White" LEDs.

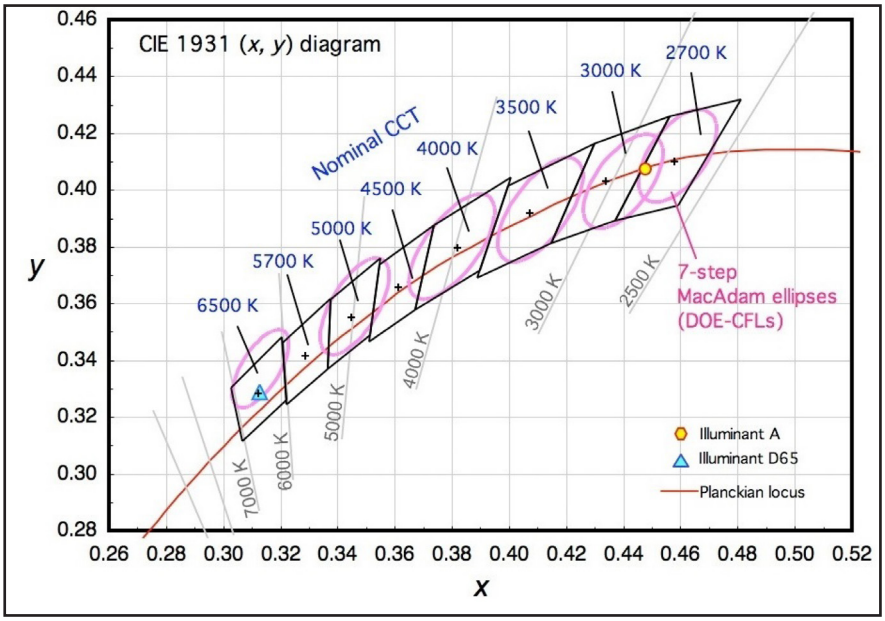


Diagram 2: MacAdam Ellipse, Chromaticity Diagram example.[4]

As the peak emission for LED phototherapy is critical - 415nm, 633nm and 830nm - all LED devices should be manufactured using the traditional binning process to ensure all LEDs are within tolerance of the desired wavelength.

The traditional binning process enables the LED component manufacturer to bin a more defined range of LEDs based on peak emission within four predefined co-ordinates, determining the area of the bin within the CIE diagram.

To further filter the produced LEDs to a selected peak tolerance range, the LEDs are then grouped by their operating voltage and optical output, typically measured in milliwatts (mW) and reported in Joules (J), this is due to optical power variations with varying running voltages which can result in irregular optical power distribution across the device.

What is a joule?

A Watt (W), the main unit of measure for optical power is defined as a rate of energy of one Joule (J) per second.[6]

[5]Example: 1W/cm^2 = 10J/m^2

Joules are the preferred metric in LED phototherapy, however, the driver of Joule based measurements is W/cm^2/S. If the optical power from a device is stable, then the only remaining variable factors are distance (determined by Inverse Square law) and time.

Optical power (mW/cm^2 and J/cm^2/S)

Optical power can be measured in various formats. Unfortunately, no set standard dictates how phototherapy devices should be measured and reported, which is why there is much uncertainty in the marketplace.

Normal practice would be to measure devices in accordance with EN 62471:2008. This European Standard gives guidelines on how to measure a device based on its normal state of application, to which the standard continues by stating the medical reporting guidelines for warning labels which must be present on the product if the optical power is equal to or more than the regulated limits of exposure.

The main factor defining the optical power exposure is determined by Inverse Square Law. Typically, this means that the closer you are positioned to a single LED, the smaller the exposure area due to the angle of light delivery, (see example below).

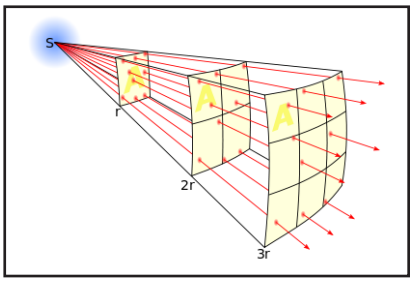


Diagram 3: Inverse Square Law.[7]

If r is an area of 1cm square and the overall optical intensity is 10mW from the LED, then area r is 10mW/cm^2.

Moving on to 2r, this is now a 4cm square area. Using the same 10mW from source, the power is now 2.5mW/cm^2. The further away from the source the more optical power required from the LED to maintain the required optical intensity.

However, being closer to the LED isn't always best.

A typical argument when discussing phototherapy is that an LED mask placed on the skin provides higher power than that of one sat further away from the patient's face; this incorrect.

While masks sit close to the skin, they do not distribute light evenly around the surface of the face. Poor distribution of light will lead to poor results and potentially overexposure of power to skin cells in direct contact with the LED point source over those in the surrounding unilluminated areas.

LEDs are the point source of power; when calculating the surface area of a mask it is clear the J/cm^2 is a lot lower than first stated due to the difference between reportable maximum powers and real-world delivered optical power over the entire device.

What are the maximum power limits across LED phototherapy devices?

To date, the highest recorded optical emission with clinical data to support the claims is:

- 415nm (typically referred to as blue light in the aesthetic medical sector) with 48 J/cm^2 over 20 minutes
- 633nm (red light) with 126 J/cm^2 over 20 minutes
- 830nm (near-infrared (NIR) light) with 66 J/cm^2 over 20 minutes

Optical power distribution

Light is one-directional, when light is forced around a curved surface of a device, it can only do so through refraction and reflection.

The typical light loss per light bounce is between 8-12% dependant on the refractive index of the material. As a result, the implied optical power stated of the device, when used in practice, drastically differs from the reported J/cm^2 initially stated.

Dermalux devices, as an example, are designed to provide a uniform optical power distribution across the LED array, this is produced via primary optics as a part of the LED and the LED layout.

The layout of the LEDs on a large area array is very important as it is the first determining factor to maximise optical power uniformity.

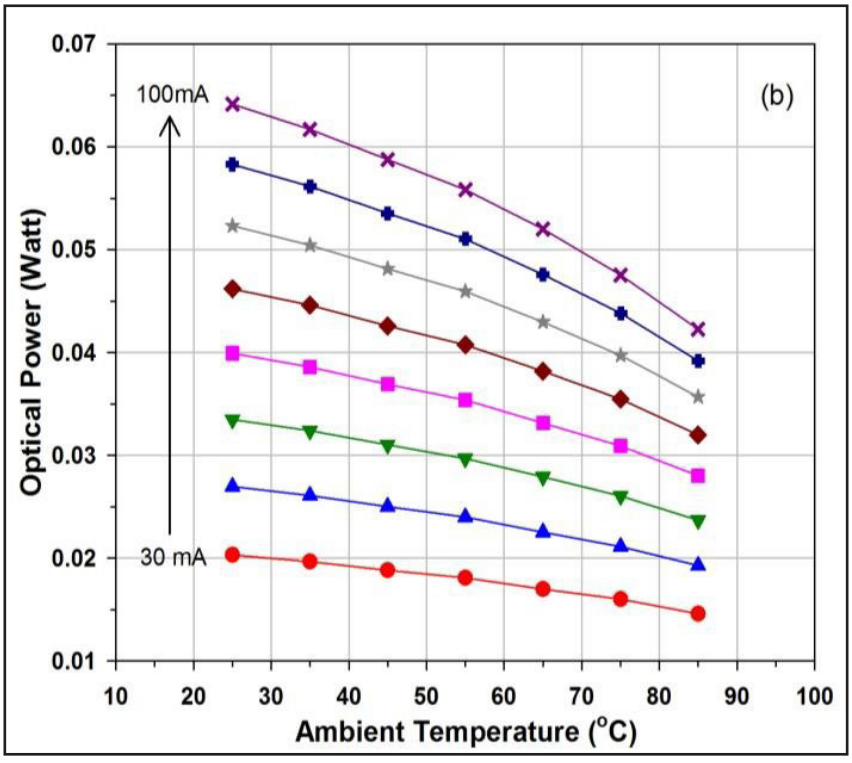
Secondly, single colour wavelength LEDs are best for a uniform optical configuration as the LED package enables the manufacturer to deliver the highest optical efficiency while maintaining thermal stability and optical uniformity.

Other products are available on the market which use twin or tri-colour LEDs; the fundamental design flaw with this solution is the volume of power driven through the LEDs. To overcompensate for optical uniformity due to the product shape, such as in a mask, the manufacturer aims to emit as much optical energy as possible from an LED source.

In principle, a twin chip LED's diode surface area is less than half the size of that of a single chip diode. As a result, the overall product lifetime is reduced due to the stress exerted across the diode and the resulting heat generated that can't be dissipated effectively to maintain optical performance, therefore the resultant optical power is reduced further. A result of thermal inefficiencies is that the peak wavelength shifts over time due to decay of the LED chip, and furthermore, the optical power decreases. In practice, the treatment received on the first use will be drastically different from the one-hundredth time of use.

The graph below demonstrates an LED's optical performance and the reduced optical power when run at varying currents and consequently varying ambient temperatures.

Diagram 4: Optical Power Relative to varying Ambient Temperatures.[9]



As the drive current is increased on an LED, more heat is generated by the diode as a result. Heat is detrimental to the optical power produced by the LED. Thus, the hotter the device runs, the less optical power is generated. A good manufacturer will take steps during the development of a device to disperse heat to ensure the LED is performing at its best, to optimise its effectiveness and overall lifetime.

Home-use devices

LED phototherapy devices for use at home must meet the requirements of Medical Device Regulations (EU 2017/745) from May 2020 which includes requiring approval to IEC 60601-1-11 and IEC 60601-2-57. Any LED phototherapy device qualified to these standards are deemed safe to use.

The Instructions For Use (IFU) provided with the device will make clear statements as to the use of the device in a home environment. Any device carrying normal CE marks and sold after May 2020 will not meet the new safety regulations in this sector.

Regulations and what to look for

Unfortunately, there has been an influx of unregulated LED devices appearing on the market. These devices can potentially pose a danger to the client, and the operator, depending on the severity of the non-conformities to basic safety regulations. Furthermore, ill-defined optical powers can lead to potential photosensitive reactions.

The Biphasic Dose Response is a proven theory which states that if insufficient optical energy is applied there will be no, or minimal, response. Conversely, if

too much energy is applied then the stimulatory response is replaced by bio-inhibition, i.e. it inhibits the cellular reaction.

In addition, focusing on the peak emission of 415nm - if an LED is of poor quality, there is a high risk that the LED may emit UV optical power. A well-defined 415nm LED will have a short wavelength boundary greater than the 405nm starting point of UV light. There is very little margin for error with a 10nm window determining optical safety.

There has been a recent change regarding insurance policies whereby practitioners are now being asked to provide CE certification for devices they use within their practice and certificates for the training they have received from the manufacturer.

Devices imported which carry CE marks do not automatically indicate compliance, be sure to recognise the differences between a medical CE mark, a regular CE mark and a China Export mark (also written as CE, but with a slightly different logo).

Medical CE markings are supported by a Notified Body number which is mandatory on all medical CE labelling across devices. If your device doesn't state a Notified Body number then it doesn't carry a medical CE certification.

Eye safety

All medical devices are subject to test IEC 62471 - photobiological safety of lamps and lamp systems.

This Standard states a set risk matrix in which the measured optical output from the device is ranked by upper and lower limits, set per category, based on peak wavelength and total optical power emitted per peak wavelength. All LED devices must state associated warnings based upon its optical power. The statement varies based on the overall optical power produced by the device as listed in the risk matrix.

A quick 'alarm bell' would be to check for this warning label - if the device doesn't have a warning label present on the product then the marketed optical data may not reflect the actual measured optical power of the device. You can, therefore, assume the device is either non-compliant or its optical power output is compliant with the lowest risk category which doesn't require a warning label.

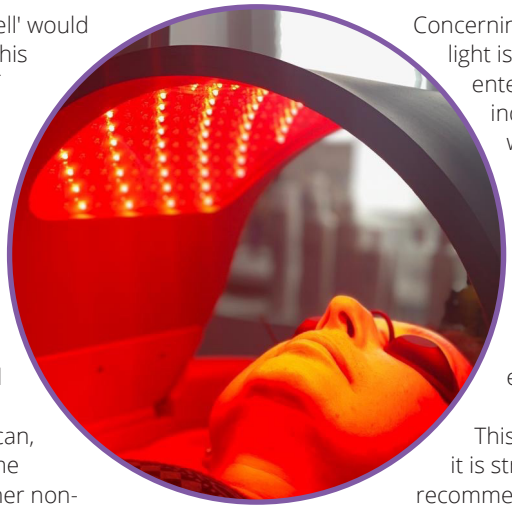
Consequently, this is a good indicator between a CE marked and a medical CE marked device and whether the medical claims are supported by its measured optical output.

In summary, if the device makes a medical claim, it must have a medical CE mark, and if there is a medical CE mark on the device, then there must be warning statements too.

LED masks are a growing concern around eye safety. I have seen several devices now being withdrawn from the market, in particular by the U.S. FDA.

Unfortunately, LED masks fall into a grey area in terms of the measurement setup. Spectrometers measure light that is exposed to the probe by directional light, any light that misses the probe passes on by, there is no correction for reflected light in this setup.

Where this measurement setup fails and should be identified in the manufacturer's risk matrix, is the real-world scenario. Sitting a mask on patient's face creates a surface area in which light can reflect off and in turn, reflect/refract across the surface of the device with an ever-increasing loss of optical power per light bounce.



Concerningly, this means light is capable of entering the eye indirectly, and with prolonged exposure to blue and NIR light over a duration of time, this can be very harmful to the eye.

This is why it is strongly recommended to wear patient goggles at all times and also for the practitioner to wear operator goggles. IEC 62471 requires both the exposure to the patient and the operator to be measured and assessed with recommendations to use protective eyewear when in use.

Key considerations when buying a phototherapy device

The best advice I can give you is to do your homework!

Always buy from a trusted and well-known brand.

Any LED phototherapy business who has the correct certifications and compliance will be more than happy to provide evidence to demonstrate conformity. They will also be able to provide initial and on-going support regarding any treatment protocols or irregularities that may occur when in use.

Do not buy cheap.

LED devices are by nature expensive due to the technology involved. If you are buying cheap, do not expect the device to have ground-breaking results.

As previously mentioned in this article, there is a maximum limit of optical power exposure to which medical devices reference their claims as predicates. However, a device with high optical power isn't the only variable to consider, you need to check the peak wavelengths of the devices as

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this is crucial for cell absorption. For further support of claims, studies can be reviewed using sources such as *PubMed*.

Do your due diligence - assess the accuracy and credibility of the manufacturer's data.

Push the manufacturer for clarification and supporting evidence as to:

- how the optical power has been obtained;
- what format has it been measured in;
- what distance from the device has it been measured at;
- what operating conditions was the device subject to, such as temperature and humidity;
- the device operating duration at the time of measurement;
- and the consistency of optical power across the array.

All this information will be available from the manufacturer as its fundamental to their technical file to achieve a medical CE mark.

Think about how you will clean the device.

A lot of devices on the market appear very aesthetically pleasing, however, in a short space of time, they will appear worn, discoloured and grubby. What will your device look like on its one-hundredth treatment?

It is best practice to refer to the Instructions For Use (IFU) when cleaning LED devices. Every manufacturer uses different materials to produce their device so the cleaning method and cleaning considerations are required to be listed in the IFU. Under normal CE marking, this is not required, however, under a medical CE, which all LED devices must be compliant to after May 2020, this is a regulatory requirement. Refer to individual manufacturers for further details on how you clean their device

Finally, consider where you are as a business, do you already have LED? Is your LED device right for your business? Are you making the most of your device?

A larger, clinically-proven device with certified medical indications would be my recommendation. Manufacturers have taken steps to ensure their devices deliver the best results and conform to regulations. Their investment in both time and money will pay dividends in your business by applying the correct device, with the right procedures and allowing the results to speak for themselves.

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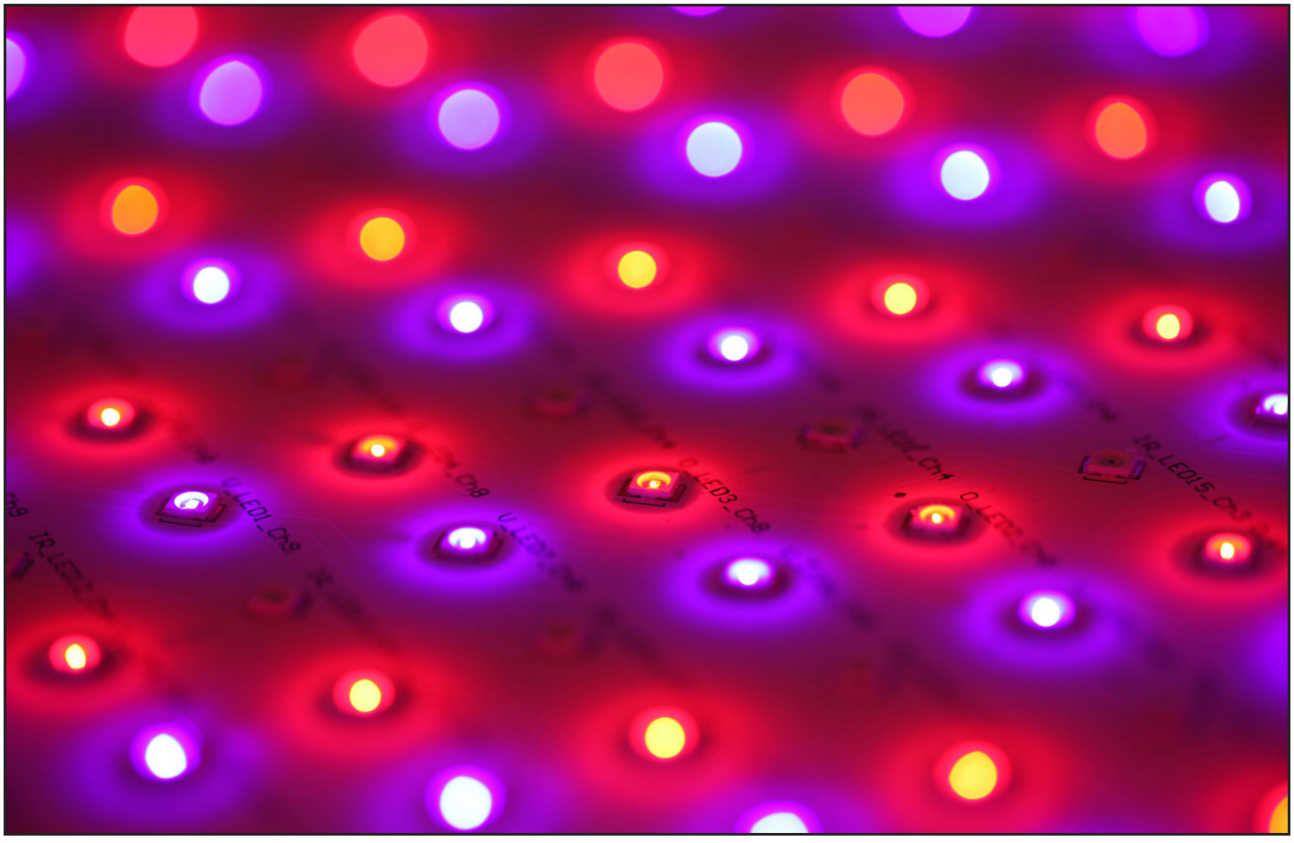

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