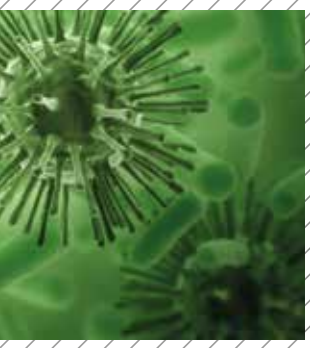
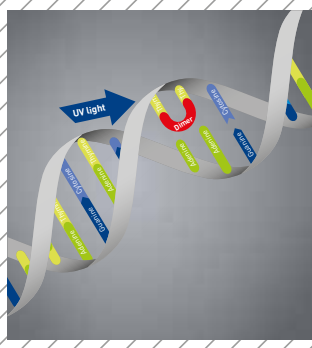
APPLICATION DEVELOPMENT

for GMP related Projects





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IST METZ

THE WORLD'S LEADING PROVIDER OF UV SYSTEMS

IST METZ GmbH & Co. KG is an internationally active medium-sized mechanical engineering company with headquarters in Nürtingen, in Southern Germany, and more than 550 employees worldwide.

For more than 40 years the company has been producing equipment for curing ink and coating by means of UV light. The UV systems cure inks, varnishes, silicones, adhesives, resins and other materials in fractions of a second. The IST Metz group of companies offers its customers the world's largest product portfolio of high-performance UV lamp and UV LED systems. The range is complemented by warm air infrared drying systems and excimer technology. IST METZ has regularly been voted the world market leader for UV curing systems since 2018.

SALES AND SERVICE WORLDWIDE

We have our own sales and service companies in France, the UK, the USA, Italy, the Netherlands, Spain, Sweden, China and Thailand and also work with a world-wide network of distributors and partners.

"eta plus electronic gmbh" develops and manufactures the UV lamps and electronic components for all IST UV systems. "S1 Optics" carries out the optical-coating of the reflectors.

The UV Technology Center allows both new and experienced UV users to benefit from working with a supplier with fresh ideas and a desire to share its UV expertise, further demonstrating our commitment to our "energy in light" philosophy.

PHARMA / MEDICAL

Efficient curing and surface treatment in the healthcare industry

Tailored systems and solutions for the healthcare industry. GMP-compliant process development, professional support and laboratory services for a variety of applications with LED and UV systems. Our services offer optimal support for the implemented systems, for example, for adhesive processes, for low-migration cross-linking of acrylic adhesives with enormously high degrees of cross-linking, for curing hydrogels. IQ, OQ and PQ are already essential components at the development phase for the customised application. Validation services can also be offered on site if required.

BENEFITS OF UV TECHNOLOGY

VOC-REDUCTION OR VOC-AVOIDANCE.

- The use of UV-curable inks and coatings is one alternative to reduce VOC-emissions and to fulfill environmental laws which will become more and more rigorous in future.
- No EX-protection necessary for curing systems and stock areas.

ECONOMY:

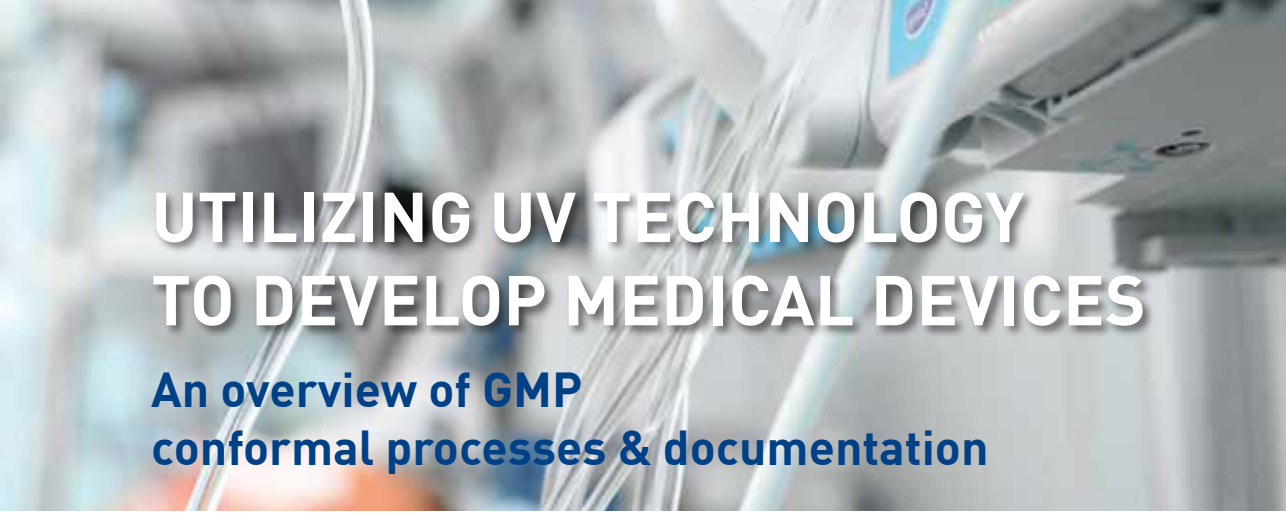
- Fast resp. immediate curing and therefore high production speeds and compact UV units.
- Low scrap rates (less parts in process by use of compact UV-units, low contamination)
- Recycling of unused inks and coatings possible (for mono-cure-systems)
- Low energy costs.

LOW SURFACE TEMPERATURE INCREASE DURING CURING.

- Process qualified for temperature sensitive materials (after acceptance test)
- No cooling down zones needed and therefore energy savings.

CAN BE PROCESSED AT ONCE, E.G. SANDING AND STACKING.

PRODUCTION OF COATINGS, WHICH ARE AT THE SAME TIME CHEMICALLY AND MECHANICALLY RESISTANT



UTILIZING UV TECHNOLOGY TO DEVELOP MEDICAL DEVICES

An overview of GMP conformal processes & documentation

Complex technical processes, used in the production of medical devices, require a need for validation if the results cannot be measured immediately. Examples for such processes are

- Sterilization,
- Aseptic packaging / assembly,
- Injection molding
- UV polymerization of adhesives and varnishes.

UV polymerization is widely accepted for its fast and reliable results, as well as its relatively uncomplicated installation and operation. It also offers the benefit of a strong cost/benefit ratio.

The rigorous guidelines of GMP conformal production supervision control demand an evaluation of these technologies, the supervisory authorities require detailed and documented validation. The scope of documentation varies whether the final product is used as a class 1, 2 or 3 product.

Where there is uncertainty about the validation requirement or scope of the validation for the critical processes / plants, the GHTF Guidelines „Process Validation“ and the recommended decision scheme[1] provide an outline to the desired validation.

1 GHTF/SG3/N99-10:2004 (Edition 2)

A workable approach is to carry out a detailed analysis with regards to an eventual risk and implement it into the existing risk management system. Risk management should be understood as a continuous iterative process throughout the lifecycle of a product that requires regular, systematic updating. A methodic approach to Risk Management has been described by ISO EN 14971. For reference tools for risk analysis are:

- Direct-/Indirect-Impact (ISPE)
- FMEA (Failure Mode Effect Analysis)
- Ishikawa (Fishbone)-Diagram
- HACCP

When the curing process can be numerically modelled, an approach to failure effects can be determined using statistical values such as 6 Sigma, knowing the parameters of the process window.

This article has the ambition to define a numerical approach, to enable UV curing technology and present a rigorous description for GMP-validation delivering reproducible and repeatable results.

A quick side note on the guiding standards: ISO 13485 vs. FDA QSR 21 CFR 820.

ISO 13485:2016 and FDA QSR 21 CFR 820 differ in several points, avoiding a harmonization in the past.

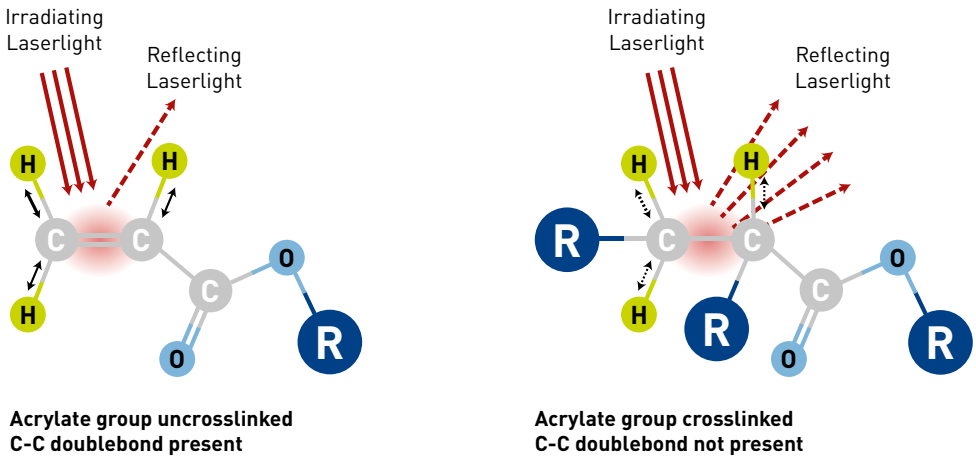
- ISO 13485:2016 is a standard based upon ISO 9001:2008 and is specific to the design and manufacture of medical devices. This standard is projected to be adopted by the Food and Drug Administration (FDA) in 2019. Originally intended to be implemented in April 2019 this step is still pending due to necessary congressional action.
- So Title 21 CFR 820 is the current quality system for medical devices used by the FDA.

Further observations in this article relate to ISO 13485 as the common international standard.

FINDING THE PROCESS WINDOW

ANALYTICAL DETERMINATION OF THE DEGREE OF CURING – FTIR SPECTROSCOPY

Fourier-Transformed infrared spectroscopy (FTIR) is a spectroscopic technique, which operates by receiving a continuous infrared spectrum of absorption or emission of a solid, liquid or gas. A FTIR spectrometer (with connected data storage) collects high spectral resolution data over the selected range, thereby capturing variations in specific wavenumbers as a derivate of the wavelength, which then quantifies the number of waves in a unit distance. At 810 cm-1 the interesting changes in acrylates can be observed, and indicate whether the material is polymerized (or not). Unfortunately the use of FTIR for Epoxies is of limited use, although it is possible to find indicators in other wavenumbers.



Acrylate group uncrosslinked
C-C doublebond present

Acrylate group crosslinked
C-C doublebond not present

Figure 1: Extinction of light in crosslinked molecules

Using this method, the crosslinking, as a result of a given dose/intensity combination, can be precisely determined. Different layer thicknesses can be determined by adequate experiment setup. The graphic contains the complete information for a given formulation from the wet state to fully achievable crosslinked state. The key information is the area under the curve as a direct proportion to unlinked acrylates, in other words the less area under the curve the more the sample is cross linked. When this information is added to a speed/UV Dose Diagram, a process window can be defined within necessary parameters.

The next step, is to determine the necessary dose/intensity combination so it is analytically defined and therefore predictable. This involves a statistical approach to determine a GMP validated process window using DoE and multivariable data analysis.

DoE

INTRODUCTION

For a company to continue to successfully evolve in existing markets, the manufacturing and production functions/processes are designed to allow ongoing innovation and ultimately optimization. Key areas are:

- Production volume
- Production development time
- Cost cutting

To drive continuous development (and the accompanying change to production characteristics and subsequent process results), design of experiments (DOE) is a tool with a clear benefits. To make this as efficient as possible, use is made of statistical methods for experimental design.

WHY STATISTICS IN THE DESIGN OF EXPERIMENTS?

When carrying out experiments to optimize production processes in industrial operations, the same measurements are not always obtained, despite careful work. Among other things, random differences (for example the base materials) play a role in the measurement conditions - the experimental results can be scattered.

In order to grasp these divergences, a central point must be defined:

- Statistics enable rational decision making despite random scatter of the measured values

Therefore, it follows, that through statistics, test differences between process and production variants are recognized and can be quantitatively assessed.

TRIALS COST TIME AND MONEY

For the given experimental design, it must be ensured - in the interests of economic feasibility - that the number of trials is in proportion to the amount of time, resources and material available that make the experiment have a reasonable return.

Typical targets are (according to literature[2]):

- project time reduction (40-75%)
- trial cost reduction (40-75%)

PROCEDURE FOR A DOE (PRINCIPLE)

At the outset of the experiment planning, all participants (R&D, marketing, production) should agree on the investigation objective, otherwise unsatisfactory results may occur.

Process results and product parameters should be translated into specific technical parameters. Of central importance here is the mean value and the statistical deviation of the measurements. Process results / product parameters themselves are suitable target values.

The quantitative knowledge of the target values and the impact on the quality of a product allow the definition of a process window which guarantees the desired characteristics of the product. Within the parameters of this process window the statistical deviations are included, so that even after worst case deviations the desired product parameters don't suffer more than the allowable and predefined tolerances.

For a robust process and product, it is then valid that disturbance factors are minimized in the production process. The dispersion of the control variables (process parameters) should be kept as low as possible, as this reduces the duration of the analysis and the associated costs.

An optimal trial design will then depend on the following parameters:

- Target sizes (see figure below)
- Amount of factors (see figure below)
- Desired accuracy of the results

2 W. Kleppmann, Experimental design – Optimizing products and processes Carl Hanser Verlag, Munich, Vienna, 2016

The more one wishes to determine the effect of the factors, the more the experimental results show deviation (the measure is the standard deviation σ), the more individual tests are required. For the factors and target sizes, the following picture emerges:

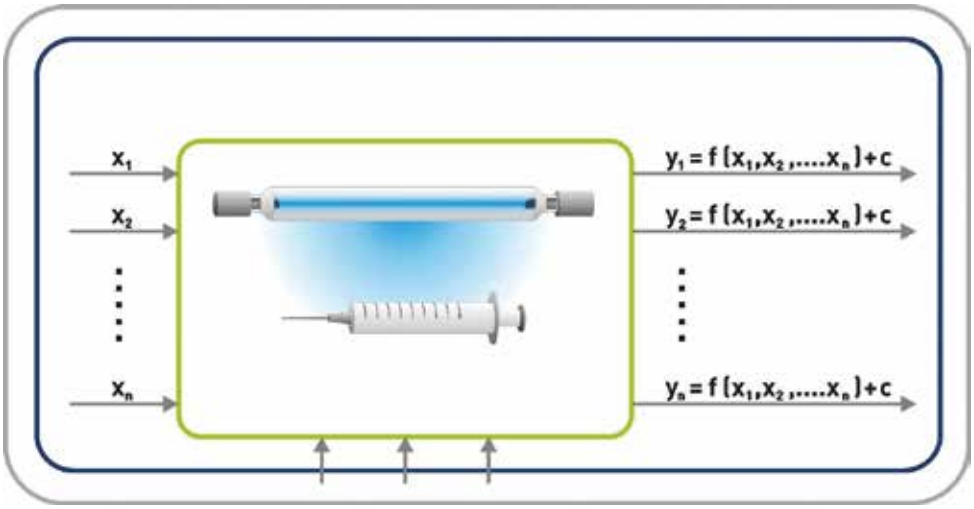


Figure 2: Factors and Targets in Process-Development

For a practical evaluation of the test results, integration of a software package is very helpful not only for analysis but also to structure the results, as this can be problematic in the experimental design, due to the abundance of information obtained.

The software (statistical analysis) can be used to determine the following parameters, among others:

- Numerical values for the size of the effects
- Width of the confidence intervals
- Statements about the significance of the effects

Once the results are technically understood, the improvements to the process can be implemented.

PRODUCTION DEVELOPMENT AND DOE (DESIGN OF EXPERIMENTS)

In order to illustrate this, a process from a known application development will be analyzed and the evaluation and interpretation will be briefly presented:

- Background and task

This particular project is to investigate UV curing of prosthetic limbs, specifically, irradiated by UV light with a plastic layer. A ‚good starting point value' can be determined with the help of a test plan (DOE).

- Evaluation of the experimental design (DOE) and conclusions

To describe an experiment successfully, quantitative or qualitative values must be determined. For a simple exposure series this might be speed, distance, lamp type etc. The test objective can be quality tests such as tensile strength, scratch resistance or other factors that are generally selected in pre-evaluation. Other variables can be added after starting the experiment, when the first correlations between different factors are calculated. The results of the resulting parameter sets can then be represented graphically.

Fig. II) versus energy. As desired, the percentage of crosslinking increases with higher energy. On the other hand, if the C = C conversion versus wavelength is plotted (Figure IV), it can be seen that the conversion is around 385nm (red tint), despite lower turnover, therefore 385nm is thus most suitable for carrying out the curing.

A three dimensional representation of the three parameters (C = C conversion, wavelength, energy) confirms the expected result, based on Figure III and IV. High energy and a wavelength of 385 nm leads to the desired high conversions.

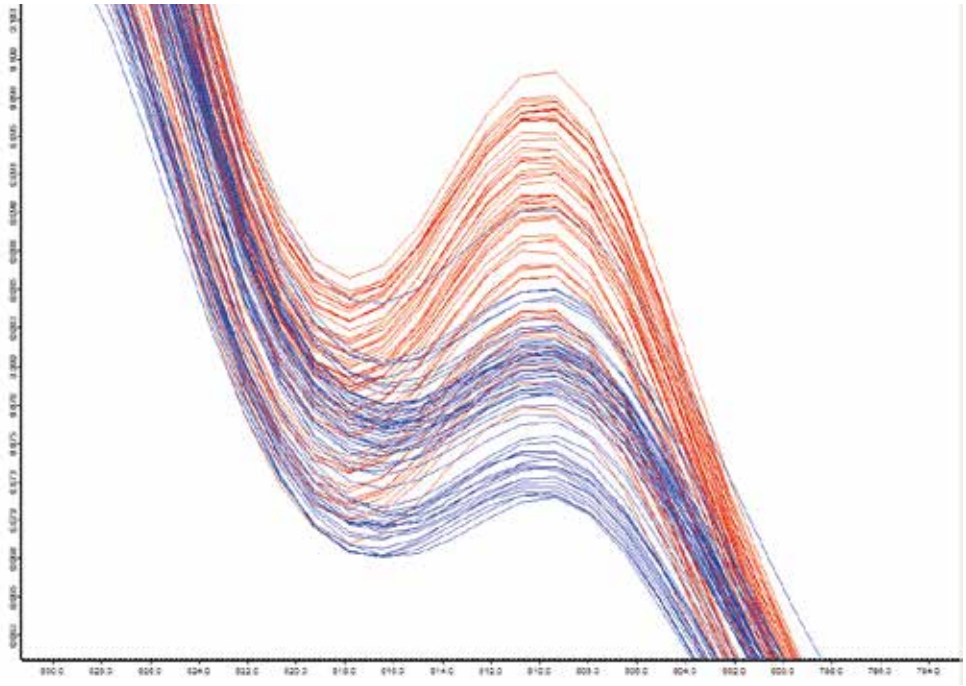


Figure 3: C = C conversion (determined by FTIR, band at 810 cm-1, of a determined set of samples.

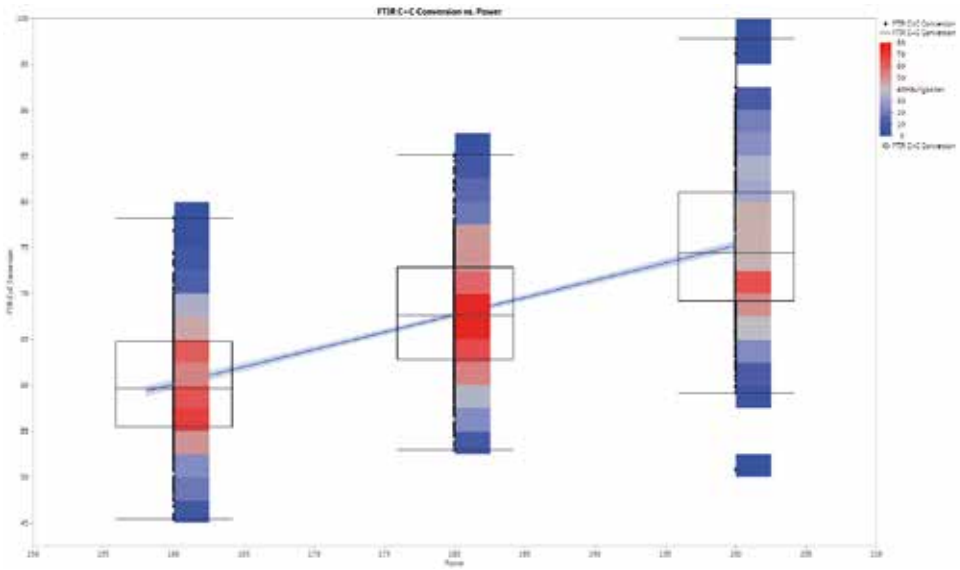


Figure 4: FTIR-C = C (%) versus energy (mJ / cm^2)

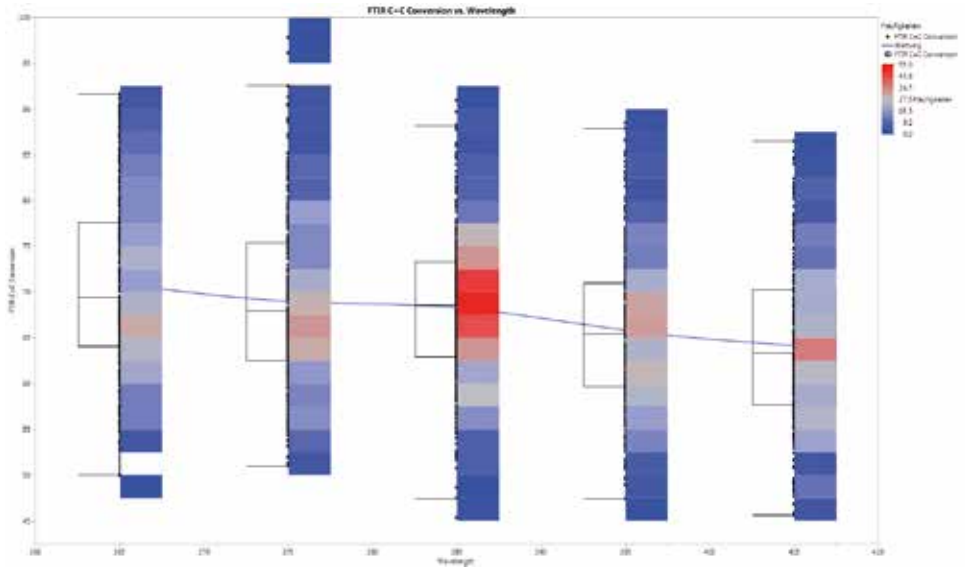


Figure 5: FTIR-C = C conversion (%) versus wavelength (nm)

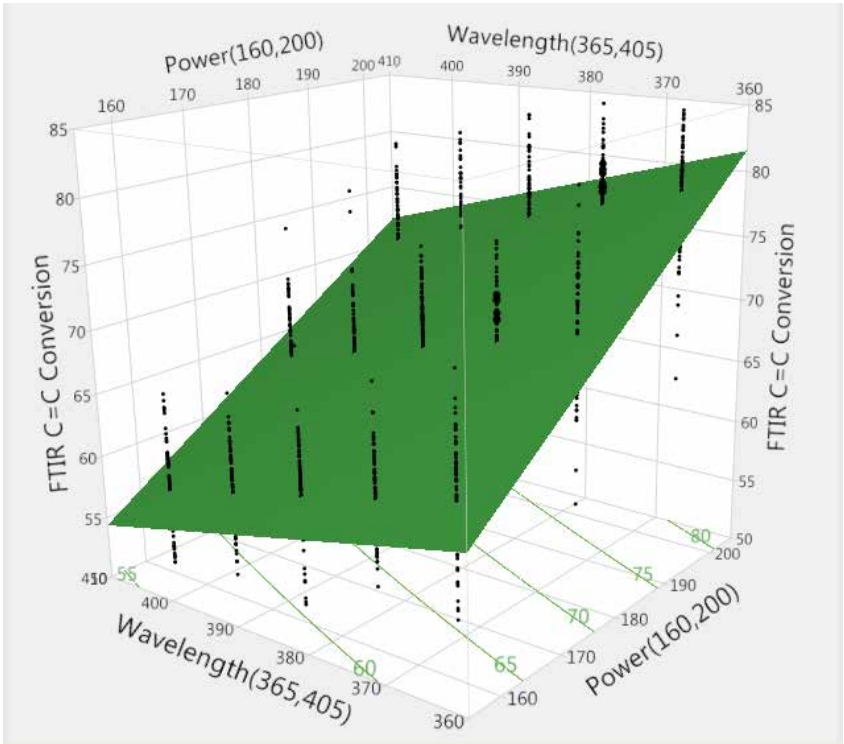


Figure 6: FTIR-C = C conversion (%) versus wavelength (nm) and energy (mJ / cm^2)

SUMMARY AND PERSPECTIVE

With the increasing speed in development, production and time to market of innovative medical devices, quality standards are a typical dilemma of manufacturing companies. One challenge in individualized mass production is identifying commonalities and making targeted use of them to minimize differences and expense in product design. An important factor here is the complete documented development of the product along the entire value chain. This allows a digital image to be created that maps all information about the product and the processes from the physical to the digital world. This not only enables efficient process design and organization, but allows measures for avoiding errors and increased efficiency.

In order to build up technical knowledge about data, however, the networking of all processes along the product life cycle is necessary. The development of a technological product description starts with the factors that have been assumed and then qualified for its development. The focus is on optimal planning, harmonizing and securing the product within the processes. With DoE, an instrument is created that enables an agile process design

The previous results will provide the basis for documentation that conforms to DIN ISO 13485 (which stipulates the requirements for documentation in the process development). This method responds to the need for consistent documentation from the beginning and allows later design adaptions. Desirability for the lowest deviations around a mean value can be found by analytical evaluation of the multivariable database and is therefore automated and excludes possible human factors. This allows a consistent setup for complex curing applications in the industry and will be an important factor in digitally describing production environments.

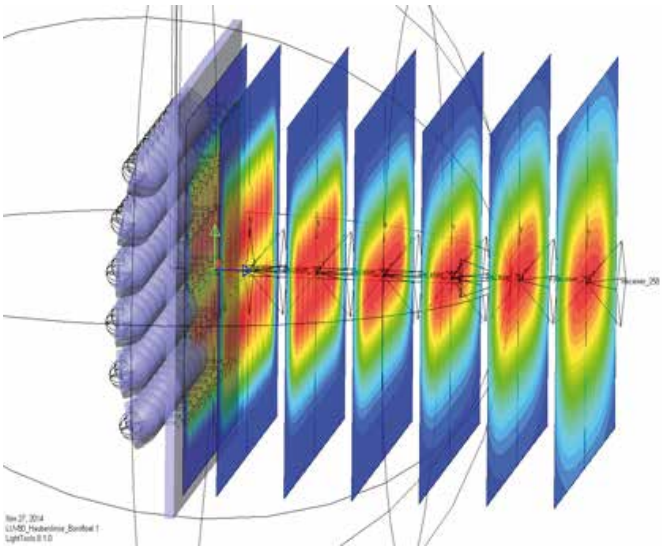
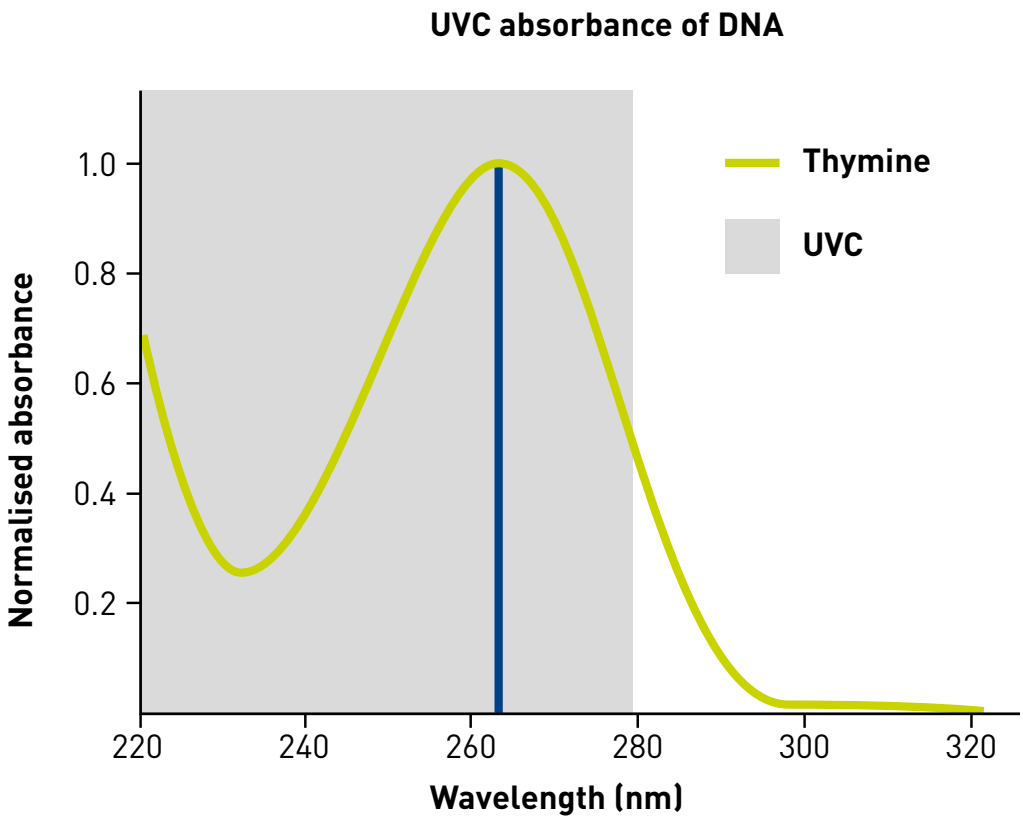


Figure 7: Numerical model of different receiver layers to determine energy distribution

DISINFECTION

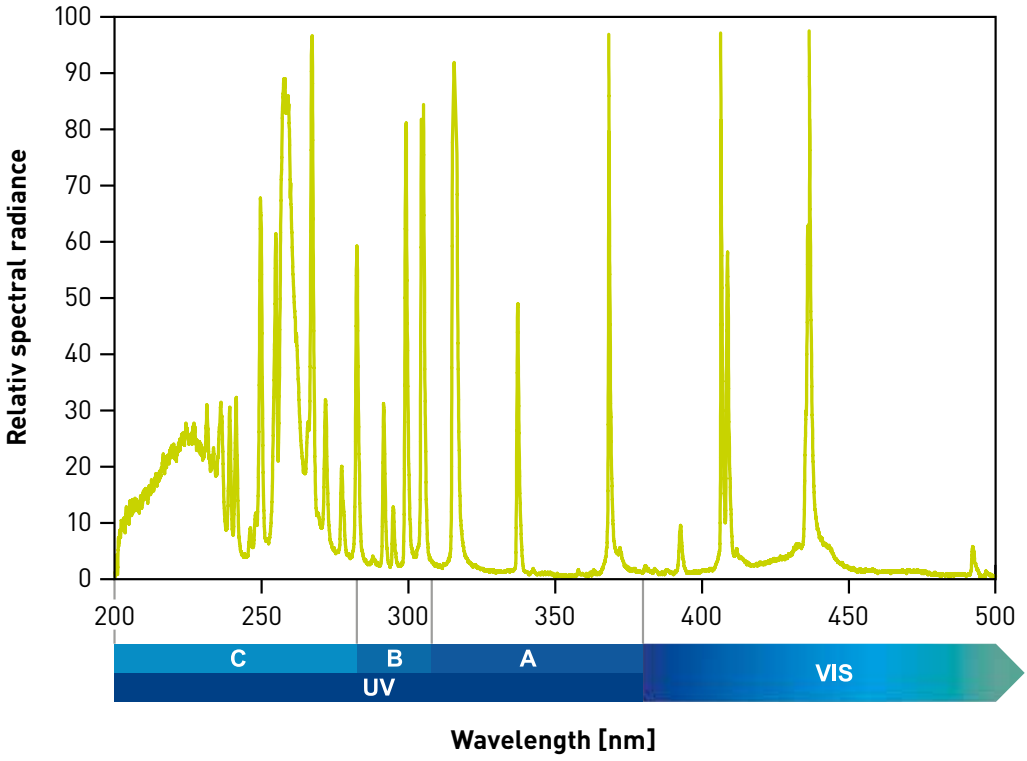
Process design for medical devices

The IST Metz Group offers UV solutions based on medium-pressure mercury vapour lamps for the reduction of microorganisms in air, water and on surfaces. The mode of action of UV-light sterilisation is based on the fact that the DNA of viruses, bacteria and moulds absorbs UVC radiation in the broadband range of 200–280 nm. The absorption maxima lies at approx. 265 nm.

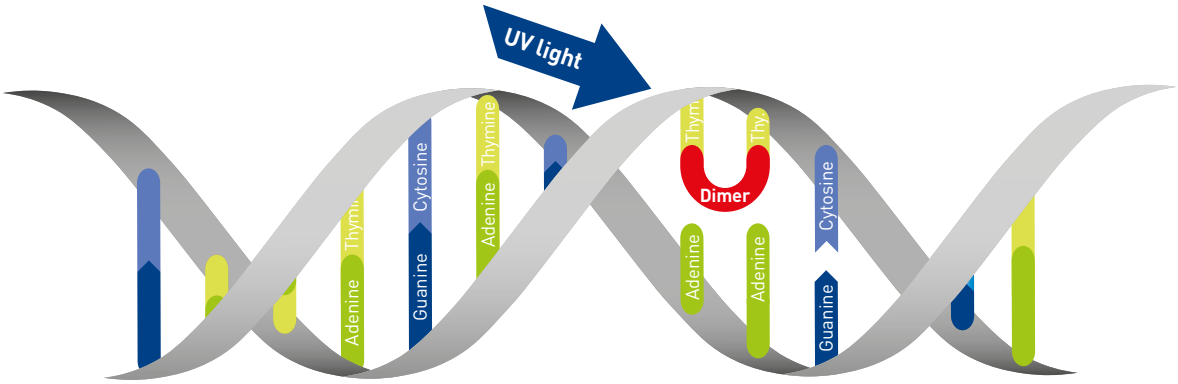


IN-HOUSE UV LAMP MANUFACTURING

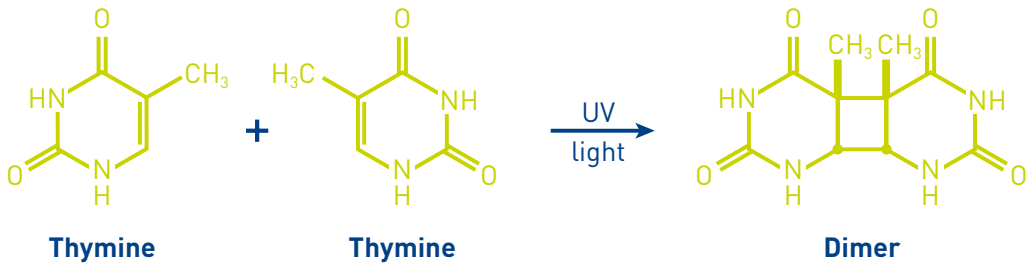
The reliability of a UV unit depends considerably on the quality of the installed UV lamps. The UV lamps are manufactured by our in-house UV lamp manufacturer “eta plus” and are designed for different industrial applications.



Exposing DNA to UV light triggers a photochemical process. In the case of two adjacent thymines, UVC light absorption destroys the connection to the opposite strand and the thymines are linked to form stable dimers.



The cell can no longer maintain its metabolism and loses its reproductive capacity. Depending on the type of microorganism and its cell structure, different UV doses are necessary to achieve the desired sterilisation effect.



Thymine **Thymine** **Dimer**

APPLICATION EXAMPLE:
STERILISATION OF LABORATORY AIR

Laboratory air at pipe outlet for 5000 m^3/h, “lamp off”

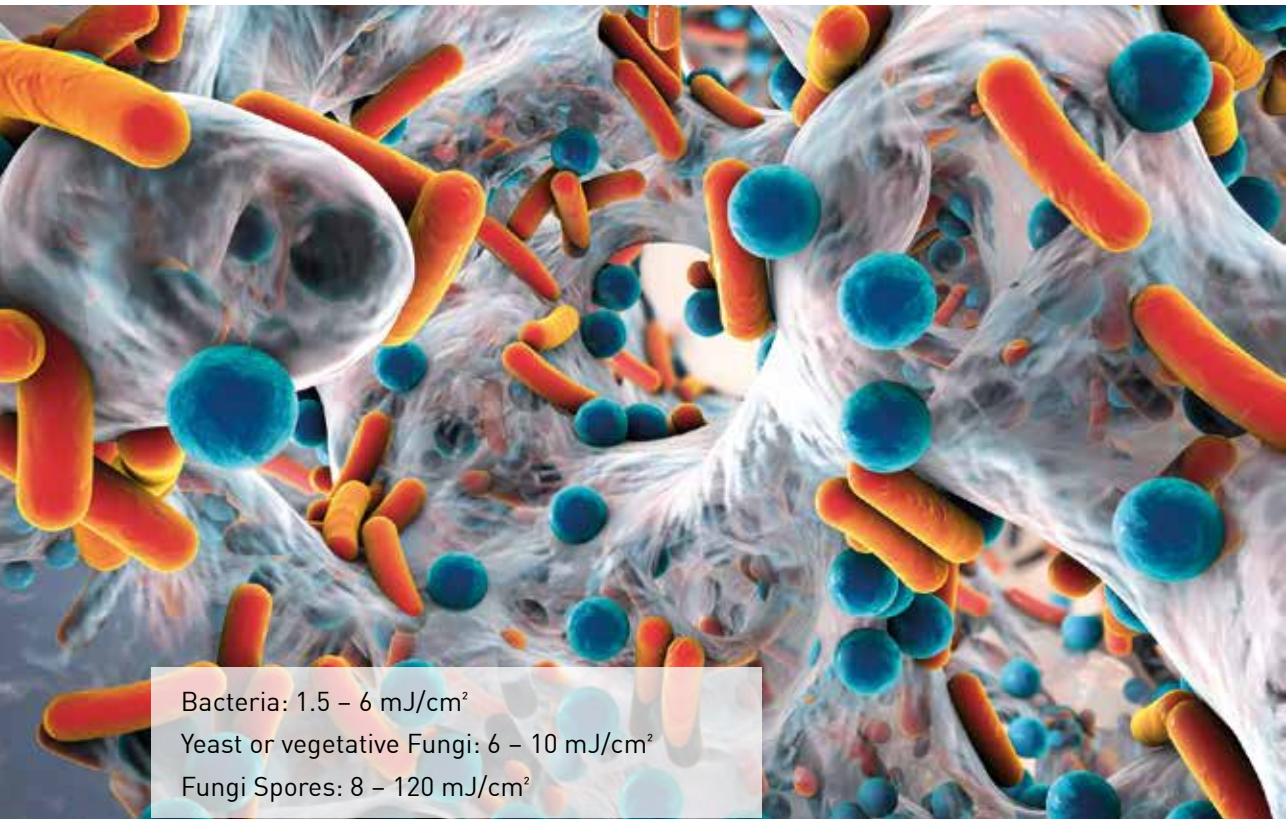
Count (bacteria/mould): 32/9; 34/7; 21/9

Laboratory air at pipe outlet for 5000 m^3/h, 6 kW lamp with 5 min flow

Count (bacteria/mould): 1/0; 0/0; 1/0

The sterilisation effect is usually indicated by so-called LD90 values. Irradiation with the specified UV dose inactivates 90% of microorganisms.

These values range from a few mJ/cm² up to approx. 120–150 mJ/cm²



Bacteria: 1.5 – 6 mJ/cm²
Yeast or vegetative Fungi: 6 – 10 mJ/cm²
Fungi Spores: 8 – 120 mJ/cm²

UV SYSTEMS FOR DISINFECTION

The BLK is a water-cooled UV unit characterized by continuous development over many years. The 7th generation of this tried and tested UV curing unit is now in use, even facilitating lamp outputs of over 200 W/cm. Minimal exhaust air quantities in operation have a positive impact on the efficiency of the overall system and reduce operating costs. The BLK is the most common UV system with a lamp length of up to 2.3 m in the industrial sphere.

URS INLAY REFLECTOR

The URS inlay technology enables optimum adaptation of the reflector geometry to the specific process technology.

HEAT-MANAGEMENT

Any heat introduced to the process is efficiently dissipated by the water cooling of the reflectors and the housing.

FLC FAST LAMP CHANGE

The cordless FLC UV lamp system enables a quick cleaning and exchange of the UV lamp.

UV ONLINE SENSOR

The integrated UV online sensor controls the current lamp power permanently and allows to check the power in the touch panel.

AT A GLANCE

ADVANTAGES OF UV

- No resistance of microorganisms to UV radiation
- Sterilisation in just a few seconds
- Chemical-free, dry method

APPLICATION EXAMPLES:

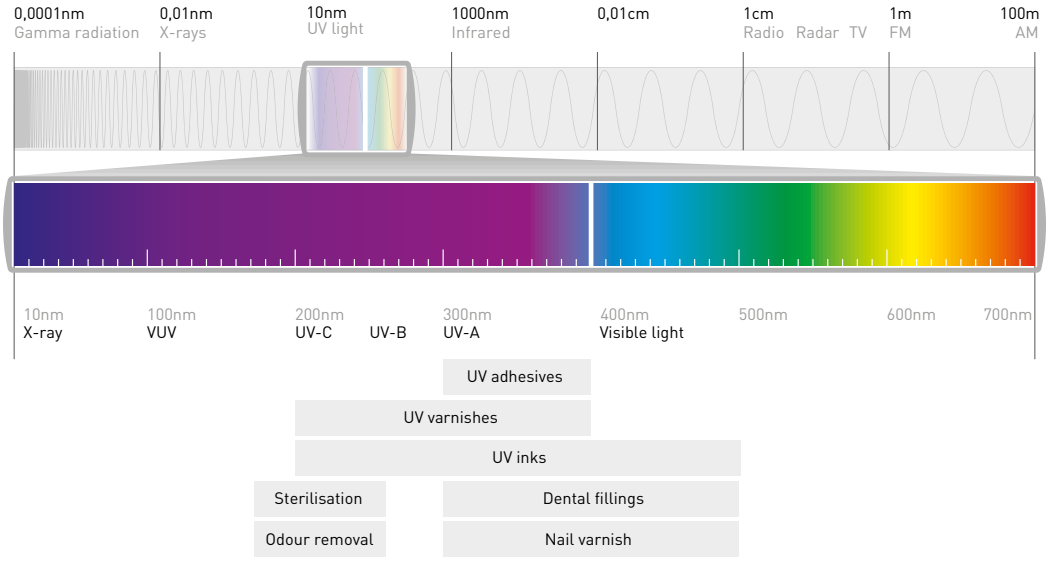
- Sterilisation of air in air supply systems
- Sterilisation of surfaces

INDIVIDUAL UV SOLUTIONS

IST UV systems can be used wherever high UVC irradiance is required.
As a manufacturer of customised systems, we offer you additional options:

- Ex-protected UV systems
- Stainless steel version
- High IP ratings
- Quartz plate technology
- Ozone-free system

IST Metz offers tailored UV units in any width, used for example in the pharmaceutical industry. In addition to the arc discharge lamps and their extremely wide emission spectrum, there has been an increasing use of LED UV technology where suitable. It is useful to use LED UV systems when selective curing or the curing of relatively small areas is required. In terms of their wavelengths and UV light intensity, the UV systems have been designed to meet the special requirements of adhesives. The particularly compact LED UV units are ready to go straight away once switched on. There is also very little heat transmitted to the substrate and they have an extremely long service life.



In the chart you can see the different kinds of UV light, which material hardens in which wavelength area or for which applications UV light is used.

SPOT LIGHT SOURCES

Precision curing in a wide range of industrial applications

Lots of our high-performance light sources and fibre optic cables have been used in the industry for many years. They are suitable for precision gluing and curing in a wide variety of industrial applications. SPOTCURE systems are used wherever short cycle times and maximum process reliability are paramount. Adhesive methods which benefit particularly from controlled light output, even in a short-wave spectral range, are those dependent on this particularly high-energy short-wave UVC light. You can use our SPOTcures both as compact device or integrated interface in your system.

SPOTCURE 01

The SPOTcure 01 UV system was specially developed for the high-precision spot curing of UV adhesives in manual bonding processes.

SAFE AND EASY TO USE

To use the SPOTCURE 01 UV system, all you need to do is press a switch on the unit. The lightguide has an anti-adhesive coating, so that vapour and adhesive can simply be wiped off its tip without problem.

SPOTCURE 05

The SPOTcure 05 UV system is ideal for use in batch production. Thanks to its closed-loop control of the light output and monitoring of sealing times, the SPOTcure 05 UV system guarantees maximum process reliability.

SPECTRUM WITH UVC

SPOTcure 05 UV systems offer a closed-loop controlled light output even in the short-wave spectral range. This is particularly suitable for bonding techniques that require this energy-rich, short-wave UVC light.

SPOTCURE 07

The SPOTcure 07 UV system is used wherever short cycle times and maximum process reliability are paramount. Exposure times of mere milliseconds are achieved without mechanical sealing systems, and thanks to its completely homogeneous, high-intensity light output, the SPOTcure 07 system is the ideal choice for multipole lightguides.

WIDE AREA OF APPLICATION

With the tight beam angle, high light output and excellent power density of the SPOTcure 07 UV system, greater distances from bonding surfaces are possible.

SPOTCURE 09

MAXIMUM PERFORMANCE AND MODULARITY

The SPOTcure 09 combines radiation power and spectral characteristics of a mercury arc lamp with the TCO and process benefits of LED technology.

Exchanging LED modules is an easy task, which enables the end-customer to adapt an SPOTcure 09 setup to changing process requirements at any time.

HIGHLIGHTS

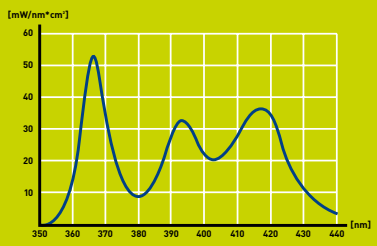
- LED process stability and TCO benefits
- customised spectral composition
- closed loop controlled output
- easy to integrate in new and existing setups
- no external cooling required

Watch now the HANDcure clip
https://bit.ly/2x13I1N

HANDcure

A mobile LED UV handset for spot and area curing

Based on the battery-powered electric tools IST has developed in conjunction with Metabo the HANDcure. With a weight of just one kilogram, tireless operation is ensured.



APPLICATIONS

- Detection and inspection of particle contamination and of material characteristics
- Curing of UV adhesives for immediate fixation, UV potting compounds, UV resins for production of composite fibers as well as UV primers and putties

SURFACE MODIFICATION

Process design for medical devices

Excimer technology is used in many industrial sectors and applications. Excimer stands for “excited dimer”, in other words a dimer (e.g. Xe-Xe-, Kr-Cl gas) which is excited to a higher energy state following application of an alternating voltage. This process physically separates at least one of the electrodes from the dimer gas by means of a dielectric barrier layer (synthetic quartz glass). The synthetic quartz glass allows transmission of UV light. To get around the problem of absorption by the oxygen in air, the process is run in an inert atmosphere which uses nitrogen.

Applications of EXCIcure technology

MATTING

Irradiating surface coatings with short-wave excimer beams polymerises the top layer, forming a thin, cured film on the surface. As polymerisation also results in shrinkage, the film close to the surface exhibits microfolds which create a matt surface. As a consequence, the formulation does not need to include matting agents. The coating is then deep-cured downstream by conventional medium-pressure UV lamps.

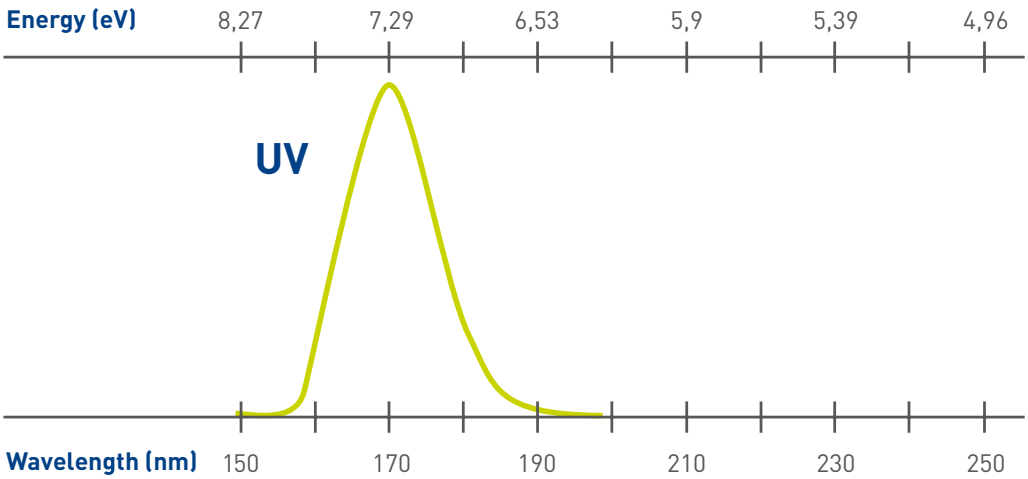
Fields of application: PVC flooring, decorative films for furniture and flooring, fibreboards and laminates, wood panels, plastic parts (e.g. automotive industry)

EXCIcure

The EXCIcure technology stands for a two-stage treatment process. In the first step, the uppermost substrate layer is polymerised with shortwave excimer beams. In the second step, the modified surface structure is cured with UV lamps.

BLEACHING AND DISINFECTION

Ozone forms at wavelengths below 242 nm. By then, the energy of the light has reached a value capable of splitting the oxygen molecule (O_2) into oxygen atoms (O). If the oxygen atoms react with an oxygen molecule, ozone (O_3) forms. Its wavelength of 172 nm and associated high-energy radiation makes an excimer a good “ozone generator”.



CLEANING AND MODIFICATION

UV cleaning methods play a key role in the display and semiconductor sector. Very short wavelength UV light is used to break up the bonds in organic substances. An additional generation of ozone oxidizes these contaminants into carbon dioxide and water. The result is a clean surface.

The modification of surfaces improves surface tension, which in turn improves wettability. Wettability is measured via contact angle.

Fields of application: display and touch panel production, wafer production

APPLICATION DEVELOPMENT

Comprehensive consulting for UV systems

LABORATORY SERVICES

We provide and share UV knowledge to our customers with application-oriented advice on any matter related to UV technology. Our aim is to work closely with customers to develop systems tailored to meet their specific requirements and to ensure the best possible integration of these into the production process. In addition to in-house trials, our laboratory is also available to customers on-site to carry out trials to establish the optimum parameters for their process before actual production starts.

Our in-house laboratory is equipped with an extensive range of different types of UV systems, including inert systems, for carrying out curing trials. With the UV laboratory units it is possible to carry out UV curing trials on a wide variety of different sized parts, which may be two- or three-dimensional. Possible applications range from the graphic arts to many industrial applications and the automotive industry.

TEST EQUIPMENT

A variety of equipment is available to test the parameters of the system and the characteristics of the inks and varnishes. It is possible to measure:

- Temperatures, UV peak and UV dose
- The surface energy level (wetability) of substrates, cross hatch adhesion, adhesion
- Density, gloss, scratch resistance, coating thickness, surface weight, etc.
- Contact angles
- C=C conversion rates by FTIR

WE ALSO OFFERS

- UV measurements
- Inerting trials
- Printability tests
- Process development
- Production of simple prototypes


Our laboratory at IST Metz

RAYTRACING TECHNOLOGIE

IST uses numerical simulation tools to define the design of an UV installation. Complex production environments can thus be evaluated and documented.

Overview of our services

In the area of application development, we offer you a comprehensive range of services tailored to your requirements. At our main location in Nürtingen (Germany), you can avail of our laboratory and extensive test equipment. In addition, we are represented around the world with our IST network.

- Dokumentation IQ, OQ
- Dokumentation by DoE
- Definition of a suitable Process Window
- Mid/Long term QC measurements (e.g. accelerated aging)

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WE HAVE THE CURE

Application Development, EN, 04/2023