Opsytec Dr. Gröbel

ICH Q1B Irradiation chamber BS-02+

Irradiation chamber BS-02+

dose controller UV-MAT Touch

The BS-02+ is a compact irradiation chamber for performing photostability tests according to ICH Q1B and VICH GL5 for medical products and active pharmaceutical ingredients. Irradiation is performed with UVA radiation and visible light according to option 2 of the ICH Q1B guideline. With a footprint of 46 x 32 cm² and a height of up to 23 cm, the irradiation chamber provides space for samples. The sample chamber temperature during operation is approx. 25 °C, so that thermal damage to the samples is avoided. Due to the high homogeneity of the irradiation, the specimens can be positioned as desired.

In accordance with the ICH Q1B guideline, modern LED light sources with a „Cool White“ emission (ISO 10977) and UVA fluorescent lamps are used. The UVA fluorescent lamps emit a maximum between 350nm and 370nm. The LED light sources emit in the spectral range from 400nm to 700nm. The Cool White light sources and the UVA fluorescent lamps meet the requirements of ICH Q1B and VICH GL5 for photostability testing of medical devices and drug substances.

Both light sources are dimmable without changing the spectral distribution and are automatically turned off after reaching the ICH Q1B target dose of 1.2 million LUX-hours and 200 Wh/m². The BS-02+ can be used to simulate the resistance to prolonged solar radiation with modern LED light sources. The old fluorescent lamps will be no longer available due to the EU regulation „Ecodesign requirements for light sources“ that becomes effective starting September 2023. For the BS-02+ we offer the irradiation control UV-MAT Touch. The irradiation control measures the UVA and the visible spectral range separately and controls a constant dose independent of aging, contamination or temperature influences.

The measurement is performed with calibrated sensors. For this purpose, the sensor already contains an extremely precise analog-to-digital converter and a temperature sensor. The sensor calibration is performed in our laboratories, for which we are accredited according to DIN EN ISO 17025.

The UV-MAT Touch records the irradiations and temperatures and can be controlled by the PC. Thus the documentation of the irradiation is possible without any problems. In summary, the BS-02+ is thus a high-quality, economical and future-proof investment for the following applications:

- Irradiation of medical products and active pharmaceutical ingredients
- Photostability tests according to ICH Q1B
- Test according to VICH GL5 (veterinary products)

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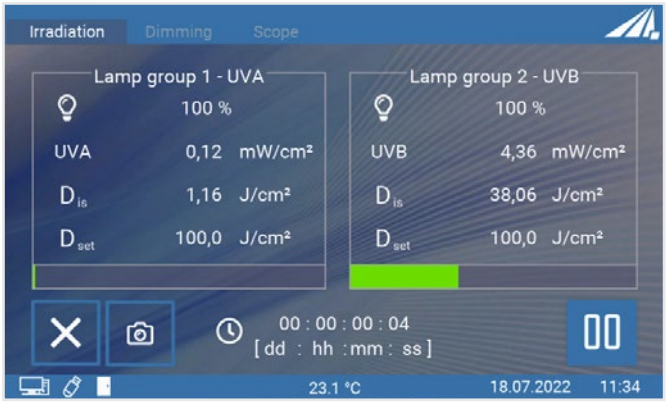
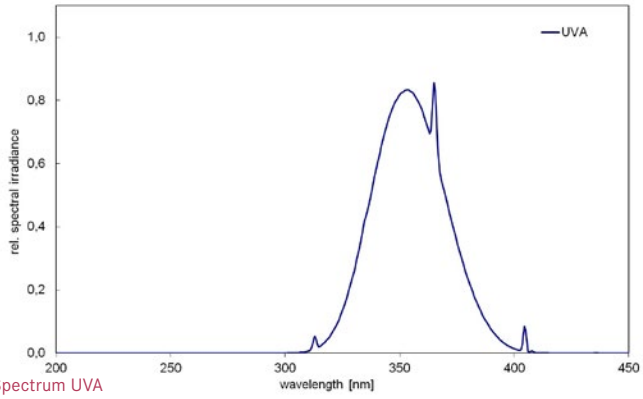
UV-MAT TOUCH

The UV-MAT Touch user interface is a high-resolution capacitive touchscreen. A powerful Cortex ARM processor ensures durability and updateability. This means that new functions can be installed directly on site. The UV-MAT Touch and the PC software are Windows 10/11 compatible.

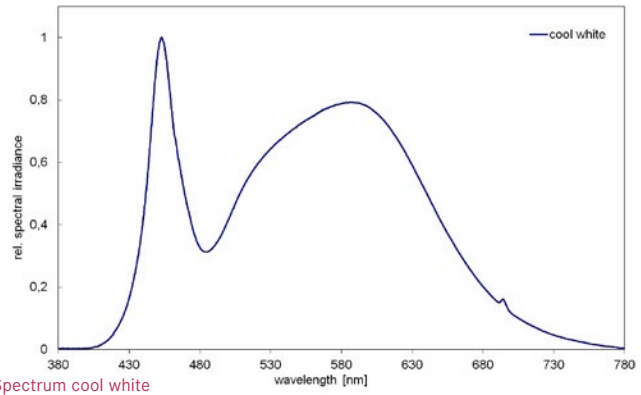
Numerical and graphical single and multi-channel irradiations, oscillograms and the settings are clearly displayed. The parameterization is done intuitively directly on the UV-MAT Touch and is password protected.



SPECTA



Spectrum UVA



Spectrum cool white

TECHNICAL DATA BS-02+

Interior chamber	46 x 32 x 23 cm
Dimensions	58 x 40 x 47 cm
Weight	~ 40 kg
Power consumption	250 W
Mains	110 - 230 V_{AC}, 50/60 Hz
Operation temperature	10 to 40 °C
Humidity	< 80% non-condensing
Lamp lifetime	LED up to 15.000 h
	UVA up to 4.000 h
LEDs	4 modules, coole white
Number of uv lamps	Typical 4, max 8
Sample temperature	25 °C +/- 5°C
Illuminance	~75.000 lux
Irradiance UVA	4 mW/cm²
Sample temperature	The cooling uses ambient air
	typically the temperaure of
	the samples is ambient + 5 °C

Indicated is the maximum irradiance with 4 UV lamps + 4 LED modules.

TECHNICAL DATA UV-MAT TOUCH

Display	Capacitive touch display
	5“ WVGA
Display output	Irradiance + dose
	Oscilloscope view
Data recording rate	adjustable: 1 s - 1 h
Recording duration	> 24000 h
Memory interface	1 USB drive (up to 32 GB)
Sensor connectors	24 bit, fully digital
Number of sensors	2
Dose range	0 - 1.000.000 J/cm²
Dose resolution	1 mJ/cm²
Irradiation duration	0,01 s to 9999 h
PC interface	USB 2.0
Sensor identification	yes
Dimensions	185 mm x 251 mm x 100 mm
Operation temperature	5 - 60 °C
Spectral ranges	UVA and LUX

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INCLUDED ACCESSORIES

The irradiation chamber is modular expandable and thus optimal for different applications.

The following functions are always included:

DOSE CONTROLLER

The irradiance is measured continuously and the irradiation is terminated by the UV-MAT at the set target dose.

The dose control UV-MAT Touch offers alternatively all functions of the UV-MAT, but simplifies the operation and documentation of the irradiations.

SENSORS

Excellent long-term stability is achieved by using suitable materials. The sensors are traceably calibrated, can be recalibrated and are delivered with factory or DAKKS calibration certificate.

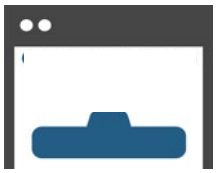
CONTROL AND DIMMING

Two groups of lamps can be controlled and dimmed separately. Example: 4 UVA and cool white LED lamps. The lamps are dimmable. The irradiance can be reduced to approx. 30%.

SENSOR HOLDER

The sensor holder fixates one or two radiometer sensors laterally in the irradiance chamber. The sensors are removable for the measurement of the irradiance on the material to be irradiated. That way, the irradiance can be determined at the desired location. Via a factor, the UV-MAT can be adjusted.

LAMPS



The UVA fluorescent lamps are easy to change, a 90° rotation is enough. The long-life LED cool white light sources are replaceable as modules.

In the BS-02+ 4 UV lamps and 4 LED modules can be used simultaneously or alternatively 8 UV lamps.

TIMER

Alternative to the dose control, we offer a settable timer. This timer is suitable for a simple irradiation between 0,01 s and 9999 h. Timer is included in the standard system.

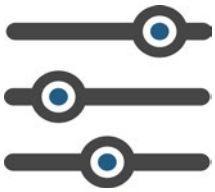
IRRADIATION LOGS

The irradiations can be recorded with a PC. The UV-MAT Touch also records irradiations on a USB flash drive without a PC.

OPTIONAL ACCESSORIES

The following functions are optionally available:

ATTENUATOR



Attenuators each reduce the irradiance to approx. 30%. We offer area attenuators and lamp attenuators. Both attenuators reduce the irradiance to 30% each.

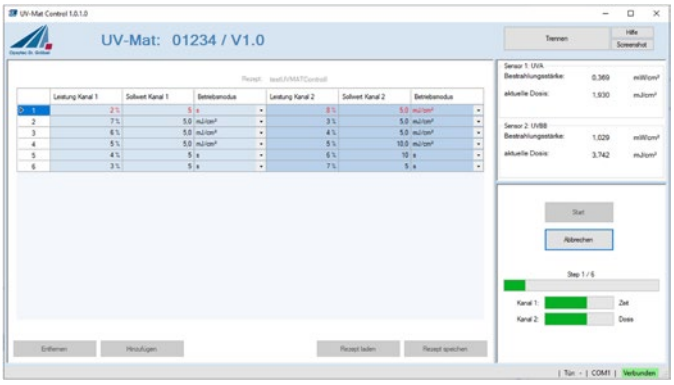
Use e.g. for the irradiation of cell cultures.

PC SOFTWARE FOR UV-MAT TOUCH

Complex, multi-stage irradiations, e.g. a pre-irradiation with UV-A at low irradiance and then a high-intensity UV-C irradiation can be easily and individually parameterized with the remote control option. Up to 30 dose- or time-controlled steps and pauses are possible.

At the same time the irradiation is logged and stored on the PC.

PC connection: USB 2.0



PART NUMBERS

BS-02+	860912	**LED module / spare LED**	860828
UV-MAT Touch	820930	**Lamps / spare lamps**	8608XX
PC-Software UV-MAT TOUCH	860901	**Attentuator for lamps**	870000
ISO 17025 calibration	17025	**Radiometric sensors**	8144XX

VIEW