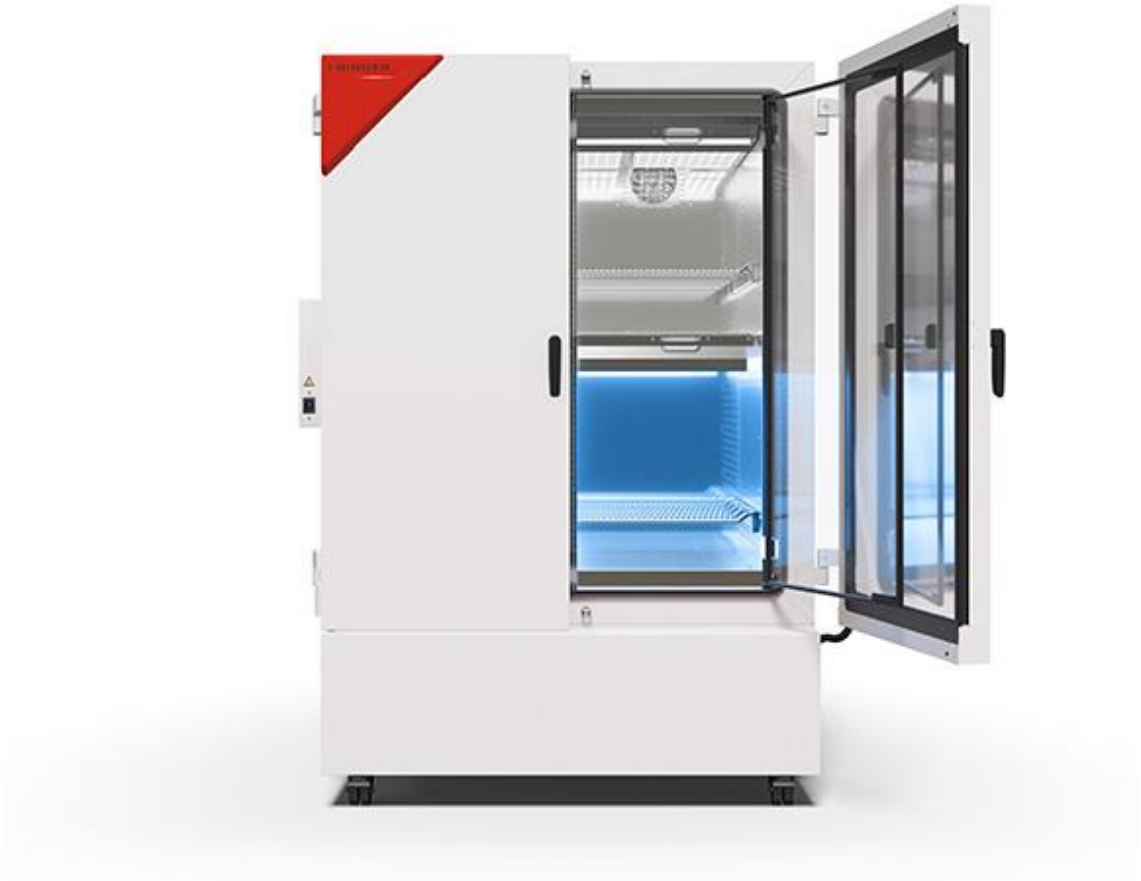
The BINDER ICH lighting system

Photostabiliy tests according to ICH Guideline Q1B

The ICH Guideline Q1B describes the basic procedure for testing the photostability of new active substances and finished medicinal products containing new active substances. A spectrum (CIE D65) that comes close to “daylight gray” under an overcast sky is suitable as an artificial light source. The ICH guideline leaves it open whether a single light source is used to generate the entire D65 spectrum and the samples are irradiated in one step or whether this is done in two steps with two different light sources (visible light and UVA). Light doses of 200 Wh/m² for UVA and 1.2 Mlx h for visible light (VIS) must be achieved.

The new BINDER ICH lighting system

The new ICH light system for photostability tests in accordance with ICH Q1B has been specially developed for the latest generation of BINDER climate chambers. The BINDER ICH light modules are perfectly matched for use in the climate chambers of the KBF, KBF PRO and KB PRO series with development level E7, each in sizes 260, 470 and 720.



Each ICH light module consists of a supply unit, which is attached to the prepared device side wall, and one light cassette each for the white light range (VIS) and the UVA range. The light qualities have been proven to meet the requirements of ICH guideline Q1B.

BINDER ICH light modules in two versions

The new ICH light modules are available in two functional variants with and without light dose control (LQC). In both cases, the light is controlled via the device controller.

- **ICH light module without light dose control**

  The ICH light module is connected to the climate chamber via a data cable. This makes it possible to control the irradiation duration of the light cassettes individually with a time segment program via the program controller of the climate chamber.

- **ICH-LQC light module with light dose control**

  The ICH-LQC light module contains two spherical light sensors in addition. The VIS sensor measures the illuminance of visible light and the UVA sensor measures the irradiance of UVA light. Both sensors evaluate the light with a spherical characteristic, which is useful for three-dimensional test objects. The light dose must be increased by a factor of 1.5 for photostability tests on flat test objects, such as printed products.

  The ICH light module is also connected to the climate chamber via a data cable and the light control runs via the program controller. The light dose to be achieved for the two types of light is entered in the controller (typically 1.2 Mlx h visible light and 200 Wh/m² UVA) and the light cassettes are automatically switched off individually once the dose has been reached.

The irradiance and illuminance levels of the BINDER ICH light modules are designed so that a complete ICH photostability test can be performed in two days. The light intensities were limited in such a way that thermal effects can be excluded during the photostability test.

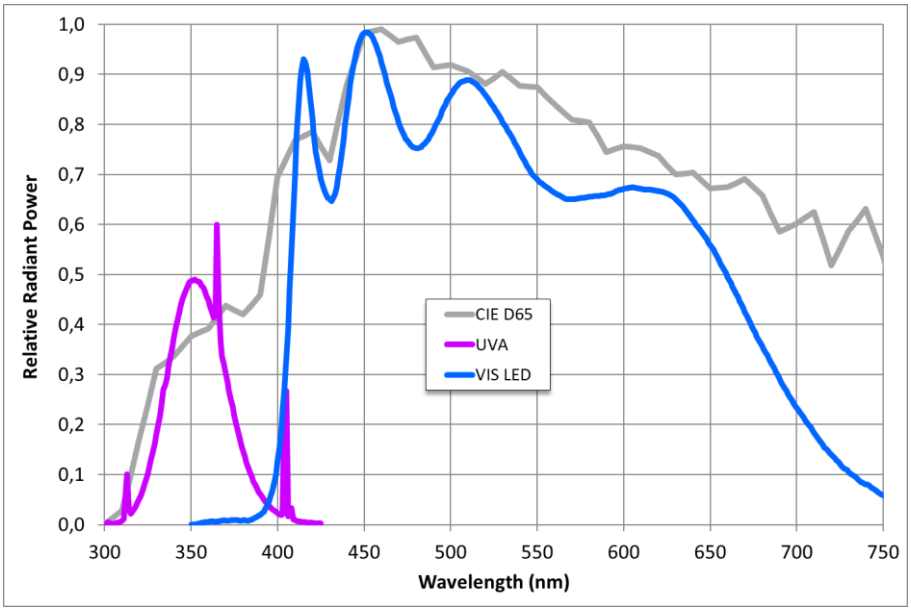
Scope of delivery of the BINDER ICH light modules

- VIS light cassette with connection cable
- UVA light cassette with connection cable
- U-rails for mounting the light cassettes in the climate control cabinet
- Supply box with ballasts/power supply units
- Profile rails and bolts for attaching the supply box to the climate chamber
- Data cable
- Mains cable
- Operating instructions
- ICH-LQC light module only: Spherical VIS light sensor for light dose control
- ICH-LQC light module only: Spherical UVA light sensor for light dose control

Emission spectra of the light cassettes

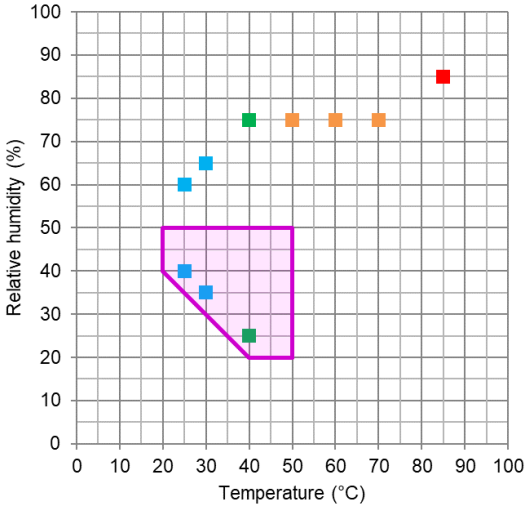
The latest LED technology with spectral characteristics similar to sunlight is used in the white light cassette (VIS). The UVA range cannot be covered with current LED technology in accordance with ICH requirements, which is why special fluorescent tubes were used. The two light cassettes together reproduce the CIE-D65-like spectrum required by the ICH perfectly.

- CIE D65 spectrum (daylight gray)
- VIS light cassette: White light spectrum LED SunLike cool white 6,500 K
- UVA light cassette: UVA spectrum Narva PUVA

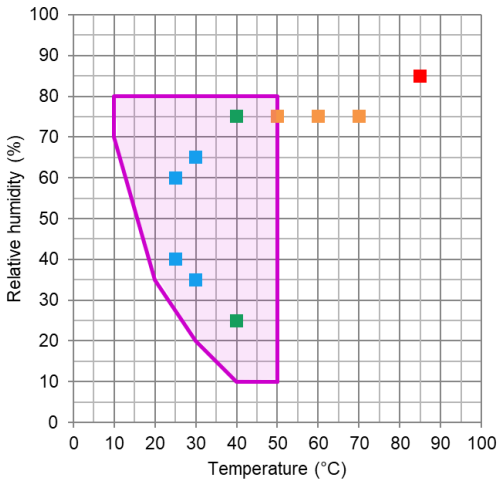


Climate diagrams of BINDER climate chambers with ICH light

KBF 720 with 100 % ICH-Light



KBF PRO 720 with 100 % ICH-Light



Compatibility with BINDER climate chambers

The ICH light modules are compatible with the climate chambers of the KBF, KBF PRO and KB PRO series in sizes 260, 470 and 720 with development status E7. The light module is installed on site by the customer or by a service partner.

	ICH Light module					
	ICH 260/470	ICH 720	ICH-LQC 260/470	ICH-LQC 720	Temperature range (°C)	Humidity range (% RH)
KB PRO 260	●		●		5 … 60	unregulated
KB PRO 470	●		●		5 … 60	unregulated
KB PRO 720		●		●	5 … 60	unregulated
KBF 260	●		●		20 … 50	20 … 50
KBF 470	●		●		20 … 50	20 … 50
KBF 720		●		●	20 … 50	20 … 50
KBF PRO 260	●		●		10 … 50	10 … 80
KBF PRO 470	●		●		10 … 50	10 … 80
KBF PRO 720		●		●	10 … 50	10 … 80

Specifications for KB PRO + ICH light module (100 % light)

	KB PRO 260	KB PRO 470	KB PRO 720
Art. No. Climate chamber 208-240 V	**9020-0434**	**9020-0435**	**9020-0436**
Inner volume (L)	262	472	727
Inner width (mm)	656	656	1.011
Inner height (mm)	695	1.250	1.250
Inner depth (mm)	575	575	575
Temperature range with light (°C)	5 … 60	5 … 60	5 … 60
Humidity range with light (% RH)	unregulated	unregulated	unregulated
Art. No. ICH Light module	**8012-2441**	**8012-2441**	**8012-2442**
Art. No. ICH-LQC Light module	**8012-2443**	**8012-2443**	**8012-2444**
VIS-Illuminance (klx)*	38	38	42
UVA-Irradiance (W/m²)*	37	37	51
ICH Q1B test duration (hours)	32 + 6 = 38	32 + 6 = 38	29 + 4 = 33
Power supply for ICH Light module		120-240 V / 50-60 Hz	

Specifications for KBF + ICH light module (100 % light)

	KBF 260	KBF 470	KBF 720
Art. No. Climate chamber 230 V	**9020-0479**	**9020-0480**	**9020-0481**
Art. No. Climate chamber 120 V	**9020-0495**	**9020-0496**	**9020-0497**
Inner volume (L)	262	472	727
Inner width (mm)	656	656	1.011
Inner height (mm)	695	1.250	1.250
Inner depth (mm)	575	575	575
Temperature range with light (°C)	20 … 50	20 … 50	20 … 50
Humidity range with light (% RH)	20 … 50	20 … 50	20 … 50
Art. No. ICH Light module	**8012-2441**	**8012-2441**	**8012-2442**
Art. No. ICH-LQC Light module	**8012-2443**	**8012-2443**	**8012-2444**
VIS-Illuminance (klx)*	38	38	42
UVA-Irradiance (W/m²)*	37	37	51
ICH Q1B test duration (hours)	32 + 6 = 38	32 + 6 = 38	29 + 4 = 33
Power supply for ICH Light module		120-240 V / 50-60 Hz	

Specifications for KBF PRO + ICH light module (100 % light)

	KBF PRO 260	KBF PRO 470	KBF PRO 720
Art. No. Climate chamber 208-240 V	**9020-0440**	**9020-0441**	**9020-0442**
Inner volume (L)	262	472	727
Inner width (mm)	656	656	1.011
Inner height (mm)	695	1.250	1.250
Inner depth (mm)	575	575	575
Temperature range with light (°C)	10 … 50	10 … 50	10 … 50
Humidity range with light (% RH)	10 … 80	10 … 80	10 … 80
Art. No. ICH Light module	**8012-2441**	**8012-2441**	**8012-2442**
Art. No. ICH-LQC Light module	**8012-2443**	**8012-2443**	**8012-2444**
VIS-Illuminance (klx)*	38	38	42
UVA-Irradiance (W/m²)*	37	37	51
ICH Q1B test duration (hours)	32 + 6 = 38	32 + 6 = 38	29 + 4 = 33
Power supply for ICH Light module		120-240 V / 50-60 Hz	

*The light intensities apply to spherical weighting at a distance of 12 cm from the light source. For flat samples, the test duration must be extended by a factor of 1.5 or the light dose increased by a factor of 1.5 (LQC).

Recommended BINDER accessories for cooling incubators and constant climate chambers

- BINDER PureAqua (desalination system)
  - System 8012-0759
  - Replacement cartridge 8012-0165

- Water supply set (canister solution)*
  - KBF 8012-2592
  - KBF PRO 8012-2592

The water supply system consists of a 20 L fresh water canister with level sensor, a water pump with magnetic holder for fresh water and a 20 L waste water canister

Useful BINDER options for cooling incubators and constant climate chambers

- Swivel castors, levable
  - KBF 8012-2543
  - KBF PRO 8012-2544
  - KB PRO 8012-2542

Height-adjustable castors are recommended for installation sites with uneven floors.
This option cannot be retrofitted on site.

- Object temperature controller sensor
  - KBF 8012-2591
  - KBF PRO 8012-2554
  - KB PRO 8012-2553

BINDER cooling incubators and climate chambers regulate the temperature of the supply air. Additional heat input (e.g. lighting equipment) increases the temperature in the interior slightly (by 1 to 3°C). This can be avoided by manually reducing the setpoint value or by using the “object temperature controller sensor” option. This enables precise control to the measuring point of the flexible controller sensor in the usable space. This option is particularly recommended for light/dark cycles.