

PHOTOSTABILITY CHAMBERS

ES2000 REACH-IN SERIES



REPRESENTED BY:



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INCORPORATED

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Environmental Specialties

A Luwa Group Company

PHOTOSTABILITY CHAMBERS...

an ICH discussion

The ICH Harmonized Tripartite Guideline on Stability Testing of New Drug Substances and Products is an internationally recognized document referencing the need for stability testing.

The U.S. FDA has adopted the annex document Q1B, which states that products should be evaluated to demonstrate that light exposure does not result in unacceptable changes. Should changes occur, the drug manufacturer may reformulate or repackage the product to prevent further photodegradation.

In order to comply with the Q1B guideline of 11/96, the drug manufacturer is required to use one of two optional light sources (paraphrased):

Option 1: A light source designed to produce an output similar to the D65/ID65 emission standard referenced to ISO 10977. Such sources include full spectrum fluorescent lamps, xenon, or metal halide lamps. **ES offers a custom-made full spectrum fluorescent lamp which combines visible and ultraviolet-A outputs.**

Option 2: Light sources designed to expose both cool white and near-ultraviolet light. These include:

- A cool white fluorescent lamp to produce an output similar to that specified in ISO 10977. **ES offers a custom-made cool white lamp to specifically replicate this standard.**
- A near-ultraviolet lamp with a spectral distribution from 320 – 400 nm. with maximum emission between 350 – 370 nm. Significant portions of UV should fall in the bands of 320 – 360 nm. and 360-400 nm. **ES also offers a custom-made ultraviolet-A lamp to meet these specific emission guidelines.**



CONDITIONING SYSTEM

ES' precise air control system ensures conditioned air is distributed uniformly across your product shelves. A stainless steel impeller moves the air through the conditioning components within the enclosed plenum. Air is then distributed and returned through the plenum's side wall ports which are specifically arranged for maximum uniformity and efficient thermal transfer.

The conditioning system features include:

- Temperature control to within $\pm 0.2^{\circ}\text{C}$
- Relative humidity control to within $\pm 0.7\%$ RH
- Temperature uniformity of $\pm 2.0^{\circ}\text{C}$
- Relative humidity uniformity of $\pm 5.0\%$

ES offers illuminated photostability chambers designed for high-demand testing, biological growth, aging, or conditioning. The "L" chamber series includes four standard models with temperature ranges of 20–40°C, RH ranges of 30–75%, and internal volumes of 12 ft.³ (benchtop) and 33 ft.³ (upright floor model). Flexible fluorescent light systems are available with cool white, near-ultraviolet, full-spectrum or combination cool white/near ultraviolet bulbs. The benchtop model can accommodate one light bank, and the upright floor model can accommodate three light banks.



CABINET CONSTRUCTION

Our double-wall chamber construction provides you with years of continued, trouble-free use. The interior is heliarc-welded at the seams to form a hermetic seal which prevents moisture from migrating into the insulation. Each chamber size is proportioned to allow you ease of passage through a standard doorway. Construction features and options include:

- Heavy-gauge stainless steel interior with scratch-resistant enamel on exterior of cabinet.
- Closed-cell urethane insulation for superior high/low temperature stability and minimal heat transfer. The door is also completely foamed for thermal performance and rigidity.
- Heavy-duty door hinges, full peripheral magnetic door gaskets and positive action latch with a lock to maintain a secure, uniform seal.
- Removable stainless steel plenum cover and wall air chases for ease in cleaning and maintenance.
- Heavy-duty 2" casters (on floor models) and adjustable leveling feet for ease in installation.
- Highly reflective specular metal wall coverings on all vertical surfaces.

PROPORTIONAL REFRIGERATION SYSTEM

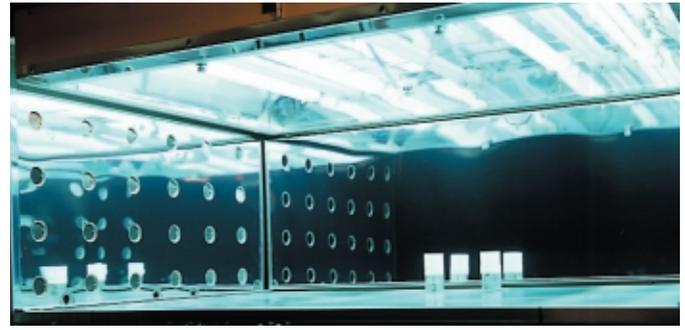
ES incorporates a proportional liquid/hot gas refrigeration design to maintain close tolerance temperature control and rapid acceleration to your setpoint. The compressor life is extended by modulating refrigerant flow as required. All facets help maintain the life of your chamber under photostability conditions. The proportional refrigeration system features are as follows:

- Air-cooled, hermetically sealed compressor with environmentally safe, non-toxic, CFC-free refrigerants. Optional water-cooled units are available.
- Expansion valve refrigeration control provides higher heat removal capacity than conventional capillary tube designs and provides immediate response to added heat loads.

LIGHTING SYSTEM

ES' upright floor models provide up to (3) simultaneous light studies with adjustable, uniformly-controlled light levels across your product shelves. Intensities are easily and individually controlled at each light bank with a microprocessor-based controller and a photodiode sensor to provide a fully automated, closed-loop control system. The features of each light bank are as follows:

- Automatic adjustment of lamp output to maintain intensities at varied conditions.
- Interchangeable cool white, near-ultraviolet, full spectrum, and dual source cool white/UV banks designed to meet Options 1 and 2 of current ICH/FDA guidelines. Three banks are accommodated in the upright floor model; one bank is provided in the benchtop model.
- Independent light level and timing controls are provided at each individual light bank. Light bank timers provide precise testing durations.
- Individual front reflector panels allow the chamber's door to open without disturbing tests at other light shelves (floor model only).
- Highly transparent light barrier for maximum transmission of visible and near-ultraviolet light while providing protection for the bulbs.
- Stainless steel light bank shell with specular aluminum interior for corrosion resistance and high reflectivity.
- Shelf-mounted telescoping sensor capable of accurate measurement and control of light levels through varied temperatures, product heights, and reflective conditions. Each light surface has a controlling sensor.
- Precision, silicon photodiode light sensor custom-designed by ESI and factory calibrated per NIST-traceable standards.
- Light level setpoint configuration in kilolux or watts per sq. m. with a digital light level display. Optional units available on request.
- High frequency electronic dimming ballasts offer up to 20% more efficiency than traditional electromagnetic ballasts.



ES provides high intensity, uniform light levels through the use of optimum bulb positioning, highly reflective materials, and high output biax lamps. Extensive R&D has led to the unique bulb layout suitable for uniform exposure in 7-lamp, 4-lamp and dual source operation. Special high-grade specular aluminum covers all vertical surfaces and provides ultimate reflectivity, resulting in excellent uniformity and higher light levels. The biax lamp design allows for 40 watt T-5 lamps to fit into a system normally capable of holding only 15–20 watt T-8 lamps. This means higher light levels and output per area than other competitive light chambers.



A popular feature of our lighting system is the dual source light bank. This is standard on the benchtop model, and available as an option on the upright floor model. Both cool white and ultraviolet-A lamps are integrated into one single bank and independently controlled by a corresponding light sensor for a total of two light systems at each shelf (shown above). Each source may be operated independently or simultaneously with light uniformity within $\pm 10\%$ in the standard 70% marked region (shown above).

ALARM / MONITORING SYSTEM

Our control panel features standard high/low visual and audible alarms for temperature, humidity, and lighting. The alarms offer you instant visual indication and time-delayed audible indication for quick notification. The temperature and humidity alarms automatically shut down specific mechanical equipment. The alarm monitoring system features include:

- Alarm silence function on all parameters with up to 60 minutes of delay time (individually adjusted for each parameter).
- Standard N.O./N.C. dry alarm contacts for remote monitoring of each parameter. There is one temperature, one humidity, and one general lighting alarm.



Upright floor model control panel shown with temperature and humidity control and optional three dual source light bank controls (6 total light systems).

TEMPERATURE CONTROL SYSTEM

ES' user-friendly microprocessor-based control system incorporates a P.I.D. controller with a subpanel-mounted process board. This board features an L.C.D. backlit display and 4-function membrane switchpad. The system includes digital setpoint and process display of your controlled parameters, while indicator lights monitor power and alarm functions. A non-volatile memory retains your setpoints for re-start in the event of a power failure. All controls are mounted on a hinged access panel for ease of maintenance. Features include:

- Temperature display configuration in $^{\circ}\text{C}$ or $^{\circ}\text{F}$.
- Precision, platinum RTD temperature sensor calibrated per NIST-traceable standards.



Benchtop model control panel shown with temperature and humidity control, standard dual source light bank controls (2 total light systems), and optional strip chart recorder.

HUMIDITY CONTROL SYSTEM

Our solid-state controlled electric steam humidifier maintains close tolerance humidity control. The humidity system features a direct-set microprocessor control with digital setpoint and process display for your ease of use and readability. High/low humidity capability is dependent on your model selection. See the *Humidity Performance Curve* sheet for specific ranges on each model. The humidity system includes:

- High output vapor generator with float switch actuated solenoid fill system.
- Dual refrigeration coil design for dehumidification at temperatures depicted on the *Humidity Performance Curve* sheet.
- Humidity display configuration in % RH.
- Solid-state variable capacitance humidity sensor calibrated per NIST-traceable standards.

Maintenance Service

ES' photostability chamber will provide you with years of reliable use with factory recommended preventive maintenance measures. These can be performed by your staff or by our factory-trained personnel available through a PM/CAL (preventative maintenance / calibration) contract from Environmental Specialties. Contact us for more information on our various PM/CAL programs.

Repair Service

We have factory-direct or authorized services for our complete product line. A 24-hour emergency call-in number is available for assistance. ES stocks most replacement parts at the factory, on local service trucks, and at regional centers to assure you minimal down time.

Validation Services

ES can provide complete performance qualifications on ES and competitive chambers. Our staff writes your IQ, OQ, and PQ Protocols and trained technicians perform field tests and validation qualification tests. Calibrations and test equipment used during qualifications are NIST-traceable and are provided as part of your validation services. Comprehensive reports are written to summarize your data for quick reference by your company and for regulatory agencies. Please contact a member of our Service Department for more details on how we can customize the testing you need.

Chamber Warranty

A thirteen-month warranty on parts and labor is included with ES' photostability chamber to provide you with assurance of our commitment to quality. An optional five-year compressor warranty is also available.

Leasing

Flexible leasing plans are available for all ES products. Consult us for further information on a program to fit your requirements.

OPTIONS & ACCESSORIES



Our paperless recorder provides permanent electronic record of temperature, humidity, and light conditions. Data can be downloaded directly to the screen or to your personal computer for printout or permanent disk storage.

Chart / Paperless Recorder

A compact strip chart or paperless recorder offers you a permanent record of parameter conditions. The strip chart recorder can accommodate up to 6 channels (for 12 ft.³ benchtop and 3 bank 33 ft.³ upright models) and the paperless recorder can accommodate up to 8 channels (for 3 bank dual source systems on the 33 ft.³ upright model). Special multi-chamber recording systems can be quoted upon request.

Reverse Osmosis Water System

A reverse osmosis water purification system is available to protect your chamber's humidification system from deposit build-up from untreated tap water. The system uses standard replaceable pre-filters, carbon filters and a durable reverse osmosis membrane.

Condensate Pump

A shallow pan condensate pump is available to move chamber condensate to a remote drain site.

Low Temperature Capability

An extended temperature range down to 4.0°C is available for low temperature studies. The light sensor is provided with a temperature stabilizing heat system to give you accurate responses at low temperature conditions.

4 Bank Capability

An additional light bank can be provided for a total of (4) light shelves. The product shelf height is reduced from the standard 12" to 9". The 4 bank arrangement is available only as single source, and light uniformity is specified as $\pm 15\%$.

Data Communications

Data communication capabilities are available for remote computer monitoring and control of all

parameters (temp., hum., light). The RS-485 option offers monitoring and control of parameters, while the 4–20 mA option offers remote monitoring at a reduced cost. Both are compatible with ES' *Envirotrac* monitoring system (SCADA — Supervisory Control and Data Acquisition System).

Photometer Package

Our photometer package is available for customer calibrations and verification of light levels inside the chamber. ES can offer you the same primary calibration instrument used at our factory. The light meter features highly accurate, cosine-corrected measurements, and is traceable to NIST sources.



The photometer package offers an NIST-traceable meter, a silicon photodiode sensor, a cosine correction dome, and (2) filters — (1) for cool white/visible measurements and (1) for ultraviolet-A/near UV measurements.

Low Light Level Filter

Custom low transmission filters are available for ultra-low light studies (ranging to 10% of the stated lowest levels). The special filters do not impact the spectral emission of the lamps.

Stainless Steel Benchtop Stand

ES' benchtop light chamber can be complemented with either a 30" high stainless steel stand, stainless steel single unit stand, or 48" dual unit stacking stand. Both stands are supplied with casters.



SPECIFICATIONS SUBJECT TO CHANGE WITHOUT NOTICE.

Interior Finish: 22 gauge stainless steel with specular aluminum reflective panels
Exterior Finish: Sprayed enamel over steel
Light Banks: 20 gauge stainless steel with acrylic barrier and specular aluminum reflector. Standard 12" clearance to shelf (9" clearance for 4 bank).



UPRIGHT FLOOR MODEL								
CHAMBER MODEL	INTERIOR VOLUME	TEMP. RANGE	HUMIDITY RANGE	VOLUMETRIC UNIFORMITY	4-WIRE ELECTRICAL VOLTS / Ø / AMPS	INTERIOR DIMENSIONS WxDxH	EXTERIOR DIMENSIONS WxDxH	WEIGHT LBS./KG.
ES2000 CL	33.8 ft. ³ (957 liters)	20–40°C	N/A	±2.0°C (±3.6°F)	208–230 / 1 / 30	34 x 28.5 x 60 in. (87 x 73 x 153 cm.)	41 x 34.5 x 91.5 in. (104 x 88 x 233 cm.)	800 / 363
ES2000 CDML			30–75%	±5.0% RH				895 / 406

BENCHTOP MODEL								
CHAMBER MODEL	INTERIOR VOLUME	TEMP. RANGE	HUMIDITY RANGE	VOLUMETRIC UNIFORMITY	4-WIRE ELECTRICAL VOLTS / Ø / AMPS	INTERIOR DIMENSIONS WxDxH	EXTERIOR DIMENSIONS WxDxH	WEIGHT LBS./KG.
ES2000 CL-BT	12.7 ft. ³ (360 liters)	20–40°C	N/A	±2.0°C (±3.6°F)	208–230 / 1 / 20	36 x 25.5 x 24.5 in. (91 x 65 x 62 cm.)	41 x 29 x 47 in. (104 x 74 x 119 cm.)	500 / 227
ES2000 CDML-BT			30–75%	±5.0% RH	208–230 / 1 / 30			595 / 270

Notes:

- Temperature and humidity ranges are based on 25°C / 50% RH ambient.
- Usable chamber dimensions are restricted by light bank dimensions. See "Light Bank Dimensions" below.
- Exterior height shown with casters (Upright Floor Model); and with leveling bolts (Benchtop Model). Door may be removed to decrease depth to 33" (Upright Floor Model).
- Low temp (4°C) option is available upon special request. Consult factory for more information.
- 50 Hz / 220 V, 120 V, and other special voltages are available upon special request. Consult factory for more information.

STANDARD SINGLE SOURCE LIGHT BANK MODELS			
LIGHT BANK MODEL	TYPICAL INTENSITY RANGE	FACTORY DEFAULT LEVEL	FLUORESCENT LAMP SOURCE
ES2000 cw: Cool White 400–750 nm. wavelengths	3.20–19.90 kilolux	16.00 kilolux	(7) T-5 Biax Cool White Lamps 40 W/22"
ES2000 uv: Ultraviolet –A 315–400 nm. wavelengths	8.00–37.30 W/m ²	22.00 W/m ²	(7) T-5 Biax Ultraviolet-A Lamps 40 W/22"
ES2000 fs: Full Spectrum 315–750 nm. wavelengths	3.10–12.00 kilolux	10.00 kilolux	(7) T-5 Biax Full Spectrum Lamps 40 W/22"

OPTIONAL DUAL SOURCE LIGHT BANK MODEL			
LIGHT BANK MODEL	TYPICAL INTENSITY RANGE	FACTORY DEFAULT LEVEL	FLUORESCENT LAMP SOURCE
ES2000 DS: Dual Source 315–750 nm. wavelengths	3.40–9.90 kilolux 4.30–17.80 W/m ²	8.00 kilolux 10.00 W/m ²	(4) T-5 Biax Cool White Lamps (3) T-5 Biax Ultraviolet-A Lamps

Notes:

- "Dual source light bank" not available in 4 bank configuration.
- Alternate light measurement units are available upon request.
- All low level readings are based on 4-lamp operational mode.
- Ranges are subject to change with special filtration requests.
- Dual source ranges are based on single light source operation. When operating both sources simultaneously, the low end ranges may be slightly higher than published.
- Maximum light intensity is based on measurements after 400 hours of burn-in time.
- Factory default level is based on approximately 60% (UV) and 80% (CW, FS) of maximum light intensity.

Specified Light Uniformity	Standard: ±10.0% from setpoint over 70.0% of usable shelf area. Optional 4 bank: ±15.0% from setpoint over 70.0% of usable shelf space (at lower sensor height).
Specified Light Control & Sensor Accuracy	±1.0% from setpoint (referenced to NIST traceable meter; meter error not included in accuracy)
Shelf Total and Usable Areas	Floor model: Total Area = 768 in. ² / 493 cm. ² per shelf (x3) 70% region = 538 in. ² / 3471 cm. ² per shelf (x3) Benchtop model: Total Area = 799 in. ² / 5155 cm. ² one shelf 70% region = 558 in. ² / 3600 cm. ² one shelf
Light Bank Dimensions	Floor model: 9.1 cm. H x 82.9 cm. W x 71.7 cm. D (3.6" H x 32.7" W x 27.8" D) Benchtop model: 13.5 cm. H x 88.2 cm. W x 63.0 cm. D (5.3" H x 34.7" W x 24.8" D)
Pre-Shipment Testing	At factory default light levels (or customer-specified light levels)

Environmental Specialties

Luwa

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ES2PSr.2

What features make our light chamber the perfect solution for your testing needs?

Monitoring and Control System

ES stands apart in our ability to offer a closed loop control scheme. Upon exposure to a programmed light intensity, the sensor feeds back a signal to the panel-mounted controller. The controller regulates the dimming ballasts to produce a light level equal to the control setpoint. The benefit is a steady light level through varying reflective conditions and lamp degradation. You will not only be able to read and record the output level of the light bank, but you will also be assured that the level will remain constant through each cycle with no manual adjustments.

Wide Range Light Level Adjustment

Our light banks feature a dimming system down to approximately 15% of full output. This allows you to run comparative studies at low and high light intensities. Lower level light studies can be supported with optional low light level filters.

Removable Light Banks & Sensors

Our stainless steel light banks are designed for easy removal, ballast servicing, and for bulb change-outs. The banks feature a special transmitting acrylic barrier lens to prevent bulb damage when loading/unloading the chamber. The light sensors also feature quick removal. By removing the light banks and sensors, you can run extended temperature ranges typical of other ES2000 models. Consult ES for more details on this capability.

Front Panels at Each Light Bank

Hinged front panels on each bank prevent the disruption of lighting systems when you open the cabinet door on the upright model. The panels also virtually eliminate air exchange to ambient while unloading each product shelf. This allows you to access each shelf without affecting the lighting level of other shelves running independent studies.

ES is devoted to ensuring you are completely satisfied with your photostability chamber purchase. Your questions are important, and we welcome an opportunity to speak with you about specific interests and lighting requirements. Call us today and a Sales Associate will be glad to assist you!

1-800-688-5859



Dual Source Lamp Bank Option

We can provide a **unique** system with two independently controlled lamp sources in one bank with lamps operational at the same time or independently. Product can be loaded on one shelf and receive a complete ICH exposure cycle. The dual source systems can be accommodated to suit your specific testing needs; you may order either one, two, or all three banks as a dual source. These banks provide you with great flexibility and less product rotation time.

User-friendly Light Bank Timers

ES uses **standard** light bank timers for control of exposure up to 9999 hours. The timers are easy to read and configure. The timing system provides you with accurate, automatically timed exposures with operational simplicity.

Highly Reflective Interior

Our light chambers feature a special reflective material superior to white paint and mirrored stainless steel. This material is the **only** material on the market that offers similar high reflectance levels for **both** visible and ultraviolet wavelengths. This guarantees you a highly uniform illuminated area for all bank types, regardless of the lamp source.

Factory-Documented Performance

ES performs **standard** calibrations/mapping and maintains all documentation of the lighting systems prior to shipment. You can feel confident in knowing that your lighting system is calibrated with NIST-traceable instrumentation and that the lighting uniformity is verified with our multi-step 20 point mapping procedure.



12 cu. ft. benchtop model with standard dual source lamp bank and optional recorder.