

ISO 9000 Certification and Your HunterLab Instrument Part II. Measuring Equipment

This note provides additional information regarding Section 4.2 of “Quality assurance requirements for measuring equipment,” International Standard ISO 10012-1:1992(E). Summary information was provided in Part I of this series of Applications Notes and will be quoted here. In order to be consistent with the ISO publication, you and your company (the user of HunterLab equipment) will be referred to here as “the Supplier.”

Note: This information is presented as a guide only. HunterLab makes no claims concerning your potential ISO 9000 certification and your requirements may differ slightly from those suggested here.

A. The measuring equipment must meet or exceed the performance level required by the application. Performance parameters include accuracy, stability, range, resolution, and repeatability. Suppliers are responsible for confirming that instruments are capable of performing as required, although HunterLab can provide advice on the proper instrumentation for an application prior to an instrument purchase. For example, if your measurement method requires spectral data between 360 and 750 nm, the instrument you choose must be capable of measuring in this wavelength range. HunterLab product literature and User’s Manuals list the performance specifications for each instrument it manufactures. Suppliers generally use these specifications as criteria for proper performance. Each instrument is tested by HunterLab and is certified to meet its performance specifications prior to leaving the factory after manufacture.

The example specifications shown below are taken from the HunterLab UltraScan XE product brochure. Other HunterLab performance listings will vary slightly in format. Each performance specification is explained below the picture.

ULTRASCAN XE DIFFUSE/8° SPECTROPHOTOMETER	
Performance Specifications	
SPECTRAL MEASUREMENT	
Wavelength Range	360-750nm
Wavelength Interval	10nm
Wavelength Accuracy	±75nm
Bandpass	10nm
Photometric Range	0-200%
PHOTOMETRIC	
REPEATABILITY: L*a*b* Peak to Peak, single flash on instrument white tile ¹	0.01
REPRODUCIBILITY: DE* on BCRA Series II Tile Set ² DE* Maximum, any one tile (Specular Included on BRCA Tiles)	0.05 0.35
Optical	
Light Source	Pulsed Xenon
Lamp Life	1,000,000 Flashes (minimum)
Lamp Maintenance	User Replaceable
Optical System	Dual-Beam Monitoring Sphere Wall
Monochromator	Diffraction Grating
Detector	40 Element Diode Array
6° Sphere	Diffuse Illumination
Specular Excluded/Specular Included	8° From Perpendicular, Sample Viewing Automated
Measurement	
REFLECTANCE	
Large Area View: Reflectance Port Size Measured Area	1" Diameter (25mm) 3/4" Diameter(19mm)
Small Area View: SAV Port Size Measured Area	3/8" Diameter (9.5mm) 1/4" Diameter (6mm) Automatic Switching of SAV Lens
Sample Viewing UV Control	Illuminated Sample Viewing Screen Motorized 420nm, 460nm UV Exclusion Filters
TRANSMITTANCE	
Regular And Total	Sample Path Lengths to 80mm
ENVIRONMENTAL	
Operating Temperature	40-100°F (4-38°C)
Operating Humidity	0-85% RH Non-Condensing
Power Requirements	Switchable 90-260 VAC; 47-63 Hz
Communication Interface	
HARDWARE	RS-232 Serial
Accessories	
REFLECTANCE	Use
Compression Sample Holder	For compressing fibers to obtain repeatable measurements
Wet Sample Port Plate	Provides a reflectance plate for measuring wet samples
Reflectance Shelf and Cover	To measure powders, translucent liquids, and non-solid materials
TRANSMITTANCE	
Transmittance Flow-Cell	For continuous measurement of fluids using a pumping apparatus
Transmittance Shelf	Holds transmittance cells of up to 80mm pathlength
Thin Film Holder	Allows positioning of thin films for transmittance measurements
Plastic Preform Holder	To measure the transmittance of plastic preforms
OTHER	
Footswitch	For hands-free triggering of measurements and macros
Glass Covered Sample Port	To protect sphere or samples against contamination or fouling
Port Up Stand	For top-loading of samples

¹ 20 measurements, 10 second intervals

² Targets based on population average, DE* on same

Specifications subject to change without notice.

Operating conditions

- Wavelength Range:** This is the range of wavelengths in the visible spectral range over which the instrument is capable of reading and providing spectral data. If you are interested in spectral reflectance (or transmittance) values, you should examine your instrument's wavelength range to ensure that it meets your needs. This parameter applies only to spectrophotometers.
- Wavelength Interval:** The instrument reports spectral reflectance (or transmittance) over the wavelength range in increments equal to the wavelength interval. For instance, if the instrument's wavelength range is 360-750 nm and the wavelength interval is 10 nm, spectral readings at 360 nm, 370 nm, 380 nm, 390 nm, ... , 720 nm, 730 nm, 740 nm, 750 nm can be provided. If you are interested in spectral reflectance (or transmittance) values, you should examine your instrument's wavelength interval to ensure that it meets your needs. This parameter applies only to spectrophotometers.

- **Wavelength Accuracy:** When reflectance or transmittance at a specific wavelength is read, the instrument can isolate that wavelength to within the value of the wavelength accuracy. For example, with a wavelength accuracy of 0.75 nm, a measurement taken at 420 nm was actually taken somewhere between 419.25 nm and 420.75 nm. The wavelength accuracy is determined using a stable standard (such as a didymium filter) with known consistent reflectance or transmittance peaks at specific wavelengths. This parameter applies only to spectrophotometers.
- **Bandpass:** Bandpass is the wavelength sampling interval of an instrument and is a function of the receiving optics. This parameter applies only to spectrophotometers.
- **Photometric Range:** The photometric range of a spectrophotometer is the range of spectral reflectances for which it is capable of measuring. 0% reflectance is a perfect black. 100% reflectance represents a perfect reflecting diffuser. For the example provided above, reflectance values of up to 200% can be measured. This means that spectral values for samples exhibiting fluorescence can be successfully measured, which is necessary if your samples are fluorescent. This parameter applies only to spectrophotometers.
- **Repeatability:** Repeatability is a measure of how constant measurements are on a single instrument. Generally, stable standard tiles (in this example, a white tile and a set of BCRA II colored tiles) are measured multiple times (usually twenty times) in a row and the peak-to-peak (p-p) range (difference between the largest and smallest values) for each tile is assessed. The smaller this value, the better the repeatability of the instrument.
- **Reproducibility:** Reproducibility is a measure of how close together measurements are for multiple instruments of the same type. Generally, stable standard tiles (in this example, a set of BCRA II colored tiles) are measured on a representative sample of instruments of the same model, and the total color difference (ΔE^* of the CIELAB scale) is calculated for the entire population. The smaller this value, the better the reproducibility for the instruments.

Another specification you may see:

- **Drift:** Drift is a measure of the consistency of readings over time. A number of readings of a single stable standard are made over a given time period (usually twenty minutes) and all the readings are compared to the first reading. The largest difference indicates the drift. The smaller this difference is, the lower the drift and the more stable the instrument readings.

B. This required performance must be documented and maintained. You must perform diagnostics to ensure proper operation of the instrument and take corrective action if the instrument does not meet the desired level of performance. HunterLab recommends performance diagnostics in instrument User's Manuals. Suppliers can also develop their own diagnostic testing procedures. Be sure to record all results of diagnostics.

Continuing with the example of the UltraScan XE, the following diagnostic tests and performance maintenance procedures are recommended in the UltraScan XE portions of the Universal Software manual:

- Complete standardization at least every eight hours and restandardization (setting top of scale) at least every four hours
- Check of the didymium filter regularly (wavelength accuracy check)

- Green tile check weekly (long-term stability check)
- Weekly calibration of the UV filter (setting proper position of the 420-nm UV filter)
- Assessment of the fluorescent standard every six months.

In addition, a diagnostics software program is included with Universal Software that allows the following tests on the UltraScan XE:

- Raw Signal Test (monitor of raw A/D counts)
- Instrument Status (confirmation that RAM, ROM, battery, and lamp power supply are operating properly)
- Motor Control Test (check of various motors in the instrument)
- Repeatability Test (check of tristimulus and spectral repeatability)
- Drift Test (check of stability over thirty minutes).

These last five tests are generally performed only by the HunterLab Field Service Department for assessment of an instrument problem, but instructions are available from HunterLab on request. If an instrument fails a diagnostic test or doesn't seem to be operating properly, HunterLab's Field Service Department may be called in to help correct the problem.

C. Any conditions necessary for meeting the required level of performance must be maintained. For example, if the instrument meets its performance specifications within a certain temperature range, the instrument must only be used in an area where that temperature range is maintained.

Like performance specifications, operating conditions are listed in product literature and in instrument user's manuals. In the example above, operating temperature, operating humidity, and power requirements are listed. Any conditions outside these ranges listed may result in non-specification performance.

References:

International Standard ISO 10012-1:1992(E), "Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment," *ISO 9000 International Standards for Quality Management*, 4th ed.

"Standard Practice for Computing the Colors of Objects by Using the CIE System," ASTM E 308-95, American Society for Testing and Materials.

"Standard Practice for Describing and Measuring Performance of Ultraviolet, Visible, and Near-Infrared Spectrophotometers," ASTM E 275-93, American Society for Testing and Materials.

"Standard Terminology of Appearance," ASTM E284-95a, American Society for Testing and Materials.

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