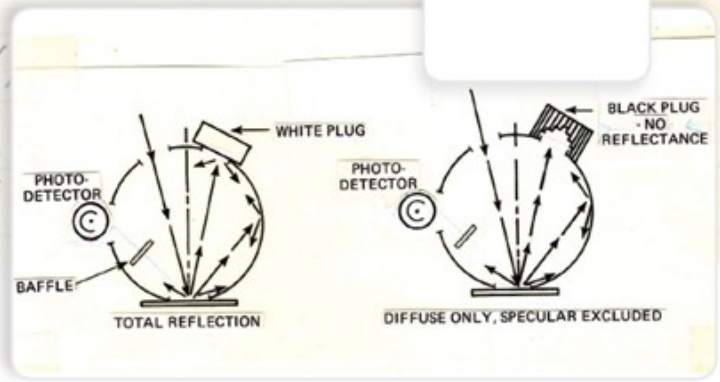
Applications Note

AN 1109



ISO 9000 Part II: Certification of the HunterLab Instrument

Each instrument is tested by HunterLab and is certified to meet its performance specifications prior to leaving the factory after manufacture.

Abstract

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."

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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 Vista product literature. Other HunterLab performance listings will vary slightly in format. Each performance specification is explained below the picture.

SPECIFICATIONS

vista®

MEASUREMENT

Measurement Principle:	Dual-beam spectrophotometer
Geometry:	Tt/0° or Td/0° per ASTM 1164, CIE 15:2018
Measurement Pathlength:	Up to 100 mm
Measurement Time:	2.5 seconds
Measurement Time with Haze:	5 seconds
Measurement Interval:	MIN 3 seconds
Port Size/Measured Area:	11 mm (0.43 in) illuminated/9.8 mm (0.39 in) measured
Transmission Modes:	Tt (TTRAN) and Td (RTRAN) and Haze

TECHNICAL

Flashes per Measurement:	4 flashes
Measurement Pathlength:	Up to 100 mm
Illumination Range:	400 nm - 700 nm
Detection Range:	400 nm - 700 nm
Spectral Resolution:	< 3 nm
Effective Bandwidth:	10 nm equivalent triangular
Reporting Interval:	10 nm
Photometric Range:	0 to 150 %
Photometric Resolution:	0.003 % (0.01 % reported)
Standards Conformance	
Colorimetric:	CIE 15:2018, ASTM E1164, DIN 5033 Teil 7 and JIS Z 8722 Condition E, G
Haze:	ASTM D1003
Light Source:	Full spectrum, balanced LED array
LED Life:	5 years typical
Sphere Diameter:	76 mm (3 in)
Sphere Coating:	Spectralon™
Spectrophotometer:	256-element diode array; high resolution concave holographic grating

PERFORMANCE

Colorimetric Repeatability:	< 0.02 ΔE* on air
Spectral Repeatability:	Standard deviation within 0.1 % T
Inter-instrument Agreement:	ΔE* < 0.15 (Avg) (Transmission Filter Set) ΔE* < 0.25 (Max) (Transmission Filter Set) ± 0.30% Measuring 10% Haze

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ISO 9001 Certified; CE Certified

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USER INTERFACE

Data Views:	EZ View, Color Data Table, Color Plot, Spectral Data, Spectral Plot, Trend Plot
Other Features:	Pass/Fail color indication, time and date stamp, auto-naming, auto-saving, data backup and recovery
Indices and Metrics:	APHA/PtCo/Hazen, ADMI, Saybolt, Gardner, ASTM D1500, Iodine, EBC, ASBC, ASBC Turbidity, Chinese Acid Wash, Lovibond® RYBN, AOCS RY, FAC, YI E313 Yellowness, YI D1925, WI E313, CIE Y Transmission, US Pharmacopeia, Japanese Pharmacopeia, EU Pharmacopeia, EP Opalescence, Haze, NTU
Color Scales:	CIE L*a*b*, Hunter Lab, CIE L*C*h, CIE Yxy, CIE XYZ
Color Difference Scales:	ΔL*a*b*, ΔLab, ΔL*C*h, ΔYxy, ΔXYZ
Color Difference Indices:	ΔE*, ΔE, ΔECMC (l:c), CIE ΔE 2000
Data Storage:	8 GB (> 1 million data records)
Illuminants:	D65, C, A, D50, D55, D75, F02, F07, F11, TL84, ULT30, ULT35
Observers:	2° and 10°
Languages:	English, Japanese, and Simplified Chinese (German coming soon)
Display:	Touch screen, high resolution 1280x800
External PC Software:	Compatible with HunterLab EasyMatch QC and EasyMatch QC-Electronic Records Quality Control Software

COMMUNICATIONS I/O

USB OTG:	Connectivity to printer, keyboard, mouse
Front Panel USB:	2.0 bidirectional, data export/import via thumb drive
Ethernet RJ45:	Print directly to standalone or network printers, Email directly from the instrument, Stream data to LIMS and SPC systems
Remote Access Support:	Enabled via internet-based support tool

PHYSICAL / ELECTRICAL

Dimensions:	Height: 177.8 mm (7.0 in.) Width: 485.8 mm (19.125 in.) Depth: 228.6 mm (9.0 in.) Weight: 6.35 kg (14.0 lbs)
Transmission Compartment:	Height: 108.0 mm (4.25 in.)* Width: 101.6 mm (4.0 in.) Depth: 187.3 mm (7.375 in.) with cover on* **Removable cover opens compartment on three sides (top, front, back) to accomodate large samples*
Base to Measurement Port Distance:	63.5 mm (2.5 in.)
Power Requirements:	100 to 240 VAC, 47 to 63 Hz, 60 W
Operating Environment:	10 to 40° C (50 to 104° F), 10 % to 90 % RH, noncondensing
Storage Environment:	-21 to 66° C (-5 to 150° F), 10 % to 90 % RH, noncondensing
Standard Accessories:	• Didymium diagnostic filter • Certificate of compliance • Power supply • VISTA Quick Start Guide • Stylus • USB Flash Drive • Cleaning Cloth

For more information, please contact HunterLab at 703-471-6870, sales@hunterlab.com or visit www.hunterlab.com

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Spectraflect is a Trademark of Labsphere
Specifications subject to change without notice

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- **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 (dE* 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 Vista, the following diagnostic tests and performance maintenance procedures are recommended in the Vista portions of the Essentials manual:

- Complete standardization at least every eight hours and restandardization (setting top of scale).
- Check of the didymium filter regularly (wavelength accuracy check.
- Weekly calibration of the UV filter (setting proper position of the 420-nm UV filter)

In addition, a diagnostics software program is included with the instrument that allows the following tests on the Vista:

- Neutral Density Test at 430nm, 570nm and 630nm
- Haze Standard Test
- Validation Test for performance on traceable standards.

These tests are usually 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.

About HunterLab

HunterLab is the technology leader in color measurement solutions, providing instruments, software, knowledge and service to a wide variety of industries.
With over 5 decades of experience in more than 65 countries, HunterLab applies our leading edge technology to your products helping you measure and communicate color simply and effectively.

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