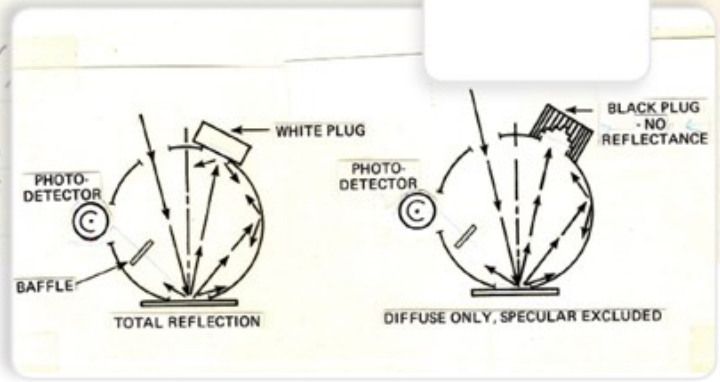
Applications Note

AN 1104



ISO Certification

It is recommended that the Supplier maintain a complete copy of the instrument service record and other related documents for potential inspection by auditors.

Abstract

"Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment," International Standard ISO 10012-1:1992(E) contains guidelines for you as a user of measuring equipment that is used to demonstrate your product's compliance with its specifications. This Applications Note provides a summary of these guidelines as they relate specifically to your HunterLab instrument.

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HunterLab

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.

The specific requirements are listed in Section 4 of the ISO document. Brief comments on each subsection are provided below.

4.1 General:

Your implementation of the requirements listed in the rest of the ISO publication must be documented. This documentation would normally include procedures for use and maintenance of the instrument and records of the performance and service of the instrument. HunterLab provides the basis for this documentation in the form of its User's Manuals, Service Manuals, and service records, but the Supplier is responsible for tailoring this general information to suit the particular application. Although HunterLab maintains service records on each instrument it manufactures, it is recommended that the Supplier maintain a complete copy of the instrument service record and other related documents for potential inspection by auditors.

4.2 Measuring equipment:

The measuring equipment must meet or exceed the performance level required by the application. Performance parameters include accuracy, stability, range, resolution, and repeatability. 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.

- **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.

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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HunterLab

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 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

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. 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.

Any conditions necessary for meeting the required level of performance must be maintained. For example, if the instrument meets it performance specification 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.

4.3 Confirmation System:

A. You must have a system in place for the management, confirmation, and use of the measuring equipment and instrument standards. This is the responsibility of the Supplier, but guidance is given by HunterLab in its User's Manuals, Service Manuals, and other documentation such as this Applications Note. This system would include information on how often and how to calibrate the instrument, how to confirm that the instrument is operating properly, and how to perform normal measurements on the instrument. You would also want to outline a maintenance schedule for the instrument and a recalibration system for the instrument standards.

An example of a method you might implement for confirmation of long-term performance of a spectrophotometer (in this case, 45/0 Instrument) is given below. Similar methods could be implemented for other types of instrument checking, calibration, and normal instrument operation.

Green Tile Check

Once a week, at the beginning of Monday's day shift, perform the green tile check as described below.

1. Standardize the spectrophotometer using the regular (1-inch) port.
2. Set up the Master Color Data display to show absolute XYZ values using the D_{65} illuminant and 10° observer.
3. Set the software to average two measurements.
4. Place the green tile face down at the instrument port. Try to center the tile at the port.
5. Read the tile.
6. Rotate the tile 90° and measure it again.
7. Look at the average of the two readings and compare it to the Values Read at Factory recorded on the back of the tile. If the read values agree with the Values Read at Factory to within $\pm$ 0.3 XYZ units for all three parameters, record the read XYZ values in the Green Tile Log and the test is complete. If any of the three read values is more than 0.3 XYZ units from the Values Read at Factory, continue with the next step.
8. Clean the white and green tiles and the black glass and then perform the test again beginning with standardization. If the values are still not within the range specified, call the authorized officer.

B. Each instrument shall have an authorized officer to ensure the operation of the unit. This officer would be appointed by the Supplier and be a member of the Supplier's staff. This person should be familiar with operation and maintenance of the instrument in order to train and supervise other operators and should be the Supplier's liaison with HunterLab in case of problems. The officer would then also have a procedure to follow which might include such steps as a repeatability check and changing the lamp. Note that the green tile readings in this example were recorded in a log. Tracking of diagnostic data in logs, trend charts, or Statistical Process Control (SPC) is recommended.

C. When the instrument or standards are replaced or recalibrated, ISO procedures must be followed. HunterLab is itself an ISO 9001- certified supplier, and so follows ISO-acceptable procedures in its manufacturing and servicing (including recalibration) processes. Also, certification that your ISO procedures may require, such as Certificates of Traceability (for standard tiles) and Certificates of Calibration (for instruments) are available from HunterLab.

Most HunterLab standards are traceable to National Institute of Standards and Technology (NIST) measurements. Notable exceptions include 20° TAPPI gloss and 75° TAPPI gloss standards and the standards for some custom modified instruments. Details concerning Certificates of Traceability will be covered in another Applications Note in this series. For customers who wish to provide evidence that their instrument is operating within manufacturing tolerances, HunterLab can also provide a Certificate of Instrument Calibration. An example is provided below.

A Certificate of Calibration attests that an instrument is in proper working condition and meets HunterLab's reproducibility specification. HunterLab recommends that a Certificate of Calibration be obtained for every benchtop and hand-held colorimeter, spectrophotometer, and glossmeter once a year (although policies of Suppliers may vary.) A certificate is obtained by sending the instrument to HunterLab's Service Department. The instrument is cleaned, and voltages, A/D counts, and other levels are adjusted as required. After all required maintenance is completed, performance testing is done and the results provided with the Certificate of Calibration. The instrument and certificate are generally returned after 3-5 business days. For more information on Certificates of Calibration, contact HunterLab's Field Service Department at 703-471-6870.

4.4 Periodic audit and review of the confirmation system:

Periodic internal audits must be performed by the Supplier and appropriate corrective action must be taken based on the findings of the audit.

4.5 Planning:

The Supplier shall ensure that the instrument to be used can meet the required level of performance for the application before commencing use of the instrument for that particular application. Instrument performance specifications are available in HunterLab product literature and User's Manuals. Knowledge of the particular application and product to be measured is the responsibility of the Supplier.

4.6 Uncertainty of measurement:

The Supplier must take into account any uncertainties associated with measurements. Uncertainties may be associated with the instrument performance, proper/improper use of the instrument, and the methodology employed for selection of samples and their measurement. Instrument performance can be gauged by examining the instrument specifications and most current diagnostic results. Assuring proper use of the instrument and an appropriate methodology for measurement are the responsibility of the Supplier, although guidelines are given in HunterLab User's Manuals and other publications such as this Applications Note.

4.7 Documented confirmation procedures:

Procedures for performing measurements and instrument diagnostics must be documented and followed. Measurement procedures used may be published standard methods such as ASTM or TAPPI methods, HunterLab's written instructions (guidance provided in the User's Manual), or a method provided by the purchaser of the Supplier's products. For tracking the performance of the instrument, statistical process control is recommended.

4.8 Records:

The Supplier shall keep records on each instrument it owns. This information should include the make, model, and serial number for each instrument and the serial number and established values for each of its standard tiles. Records should also include service records, certificates/records of calibration and traceability, expected instrument specifications, procedures and intervals for instrument confirmation, and environmental conditions required. HunterLab maintains records of each instrument it manufactures, including make, model, serial number, standard information, and service records, but it is recommended that the Supplier maintain a complete copy of the instrument service record and other related documents for potential inspection by auditors. Instrument specifications and requirements for environmental conditions can be found in product literature and/or User's Manuals.

4.9 Nonconforming measuring equipment:

Any instrument that is malfunctioning or does not meet required performance specifications must be taken out of service until the problem is corrected. HunterLab provides repair service for all its instruments until five years have elapsed since its last manufacture. If repairs are extensive or no longer available, the instrument may be scrapped.

4.10 Confirmation labeling:

Instruments should be labeled or coded with an indication of performance status. If the instrument cannot be used for any reason (e.g., it does not pass its diagnostic tests), it must be clearly marked that it cannot be used. Labeling must also include when the instrument must next be tested or calibrated. Diagnostic procedures are outlined by HunterLab in its User's Manuals and a calibration interval is recommended, but implementation of this labeling is the responsibility of the Supplier.

4.11 Intervals of confirmation:

Instruments and standards should be confirmed (tested/and or recalibrated) periodically. The period between confirmations should be established based on the stability and usage of the instrument. HunterLab can make recommendations on confirmation intervals, but the Supplier's individual needs will dictate the actual period chosen. HunterLab provides diagnostic and repair services, as well as instrument and tile recalibration. This topic will be covered in greater detail in a later Applications Note.

4.12 Sealing for integrity:

Access to adjustable settings that affect instrument performance shall be sealed to prevent tampering. HunterLab instruments are generally manufactured in such a way as to make such adjustments accessible only to HunterLab service technicians, or under the guidance of a service technician, through removal of instrument covers or access to the back of the instrument with a special tool. If there is any reason to believe tampering is possible, it is the responsibility of the Supplier to label, cover, or otherwise inform users that tampering is unacceptable.

4.13 Use of outside products and services:

The Supplier must ensure that products and services purchased meet required quality levels where they affect the quality of products to be sold to customers. Color measurement instruments are generally used for quality control of products, so this requirement definitely applies to instruments and other supplies purchased from HunterLab. HunterLab is itself ISO 9001-certified, so all instruments have been thoroughly tested under HunterLab's quality program. However, the Supplier may wish to run standard diagnostics on new or recently-serviced HunterLab instruments prior to use.

4.14 Storage and handling:

A system for handling, transporting, and storing instruments must be in place. HunterLab User's Manuals provide information on appropriate operating and storage conditions for instruments (temperature, type of surface required, etc.). When instruments are transported, it is recommended that they be returned to the original factory packaging, or, if that packing material is unavailable, pack the instrument in a sturdy, well-sealed box with at least six inches of foam or other cushioning material surrounding all sides of the instrument. The instrument should not be allowed to directly contact any surfaces of the box.

Remove the sample clamp (if you have one) from the instrument port and tape the port opening. Be sure to ship at an insured rate.

4.15 Traceability:

Instruments should be calibrated using standards that are traceable to national or international measurement standards. If such standards do not exist, suitable reference materials or industry standards are acceptable. Documentation of the chain of traceability is required. All HunterLab colorimeter standards are traceable to both U.S. National Institute of Standards and Technology (NIST) and National Physical Laboratory (NPL) of England standards. HunterLab spectrophotometer standards are in reference to the NIST perfect reflecting diffuser calibration. Gloss standards are also traceable to NIST standards (except for 75° TAPPI measurements, for which NIST does not maintain a standard). A Certificate of Traceability is shipped with each instrument that HunterLab manufactures and is updated each time standards are recalibrated. The uncertainty associated with calibrated values is also reported on each Certificate of Traceability. Replacement Certificates of Traceability are obtainable from the HunterLab Technical Services Department if required.

4.16 Cumulative effect of uncertainties:

The cumulative effect of the uncertainties of each link in the chain of calibration should be taken into account. HunterLab provides a cumulative uncertainty value on the Certificate of Traceability for your reference. This must be taken into account in one of the following ways: a) If an absolute value standard must be met (e.g., L* must be 50 $\pm$ 1 unit), the uncertainty associated with the instrument's measurement cannot be more than the allowable color variation (1 unit) OR b) The product specification can be based on a sample's *difference* from an ideal product standard. The uncertainty associated with a standard tile's calibrated values is in the absolute color (or gloss) values. If an instrument is in reasonable condition, difference measurements are generally accurate even if absolute color values are not correct.

4.17 Environmental conditions:

The instrument must be restandardized as often as required by the environmental conditions. Temperature, humidity, particulates, electromagnetic interference, and other environmental changes can cause drift, which should be accounted for. Information concerning appropriate environmental conditions for use of HunterLab instruments is given in HunterLab User's Manuals.

4.18 Personnel:

The Supplier must ensure that trained personnel operate the equipment in an appropriate manner. Personnel selection and training is the responsibility of the Supplier, although HunterLab does offer seminars and various types of on-site training, which may be personalized as needed. HunterLab User's Manuals are also helpful in training users.

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.

 11/2023

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