HIAC 9703+
SUB-VISIBLE PARTICULATE TESTING

LIGHT OBSCURATION TESTING TO USP<787>, <788> AND EP 2.9.19

- Program your SOPs into the counter
- Microsoft Active Directory User Name and Password control
- Review and Approve Workflow in the counter
- Electronic Signatures supported
- Secure Electronic Records straight from the counter

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PharmSpec Software

Program your SOPs into the counter

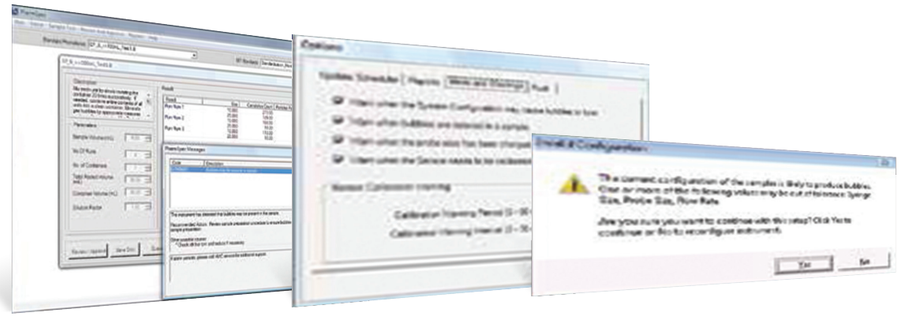
- Eliminate manual counter configuration and pass/fail calculations by using Procedure Builder to program your own SOPs into the counter so that they are available for the technician via a drop-down selection box

21CFR part 11 ALCOA Data Accuracy and Integrity

- User Name and Password credentials are controlled by your corporate IT Microsoft Active Directory
- Multi-level user rights
- Licensed software modules available to automate pass/fail compendial reporting:
  - USP<787>
  - USP<788>
  - EP 2.9.19
  - JP 11
  - JP 24
  - KP 52
- Sample result records include the technician's name, batch number, test result data, pass/fail result and SOP used for the test
- Review and Approve workflow with electronic signature to create secure electronic records straight from the counter
- Comprehensive Audit Trail included

Secure database

- You can choose to locate the database on a separate, secure networked location and the HIAC 9703+ will automatically save all records to that server across the Ethernet network
- Alternatively, you can choose to configure the 9703+ to periodically automatically back-up the database to a secure network location



Flexible sampling options

- The light obscuration sensor can be calibrated at multiple different flow rates to make sampling easier for large volume injectables/infusions testing as well as viscous fluids
- Small-bore, low tare volume sample probe available for Therapeutic Protein Injection testing and wide bore sample probe available for testing viscous samples

Use in laminar airflow cabinets

- Design allows HEPA filtered airflow from cabinet to pass over the top of the glassware/vial to help reduce the risk of sample particulate contamination from the air, reducing the possibility of false-positive results

Typical instrument configuration

PART NUMBER	DESCRIPTION
2089105-01	HIAC 9703+ sampler
2089250-150	Light Obscuration sensor
2086804-01	PharmSpec 3 software CD
700060GP	PharmSpec 3 software licence key
700057	USP Compendial Tests
700058	EP Compendial Tests
700055	SOP Procedure Builder software
2089007-025	Calibration @25mL/minute flow rate including certificate
DOC026.53.80099	IQ/OQ Validation document set on CD

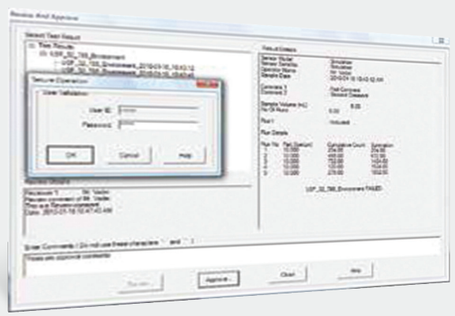
USP<787> Therapeutic Protein Injections

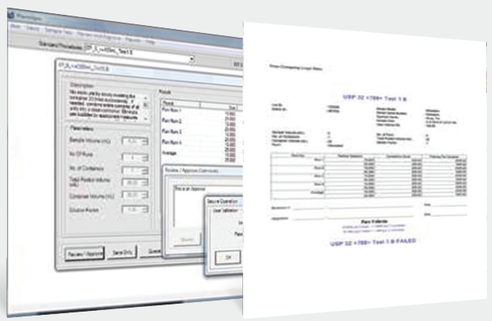
Save valuable product

- Small tare volume option of just 0.091mL allows you to get results to USP<787> with product sample volumes of just 0.2mL

Small vial clamp for conical vials

- Small vial clamp option holds conical vials in line with the sampling probe and upright for automated sampling





Specifications

9703+ Sampler

Temperature Range	5 to 40°C (40 to 104°F) 0 to 80% relative humidity, non-condensing
Temperature Range of Sample	5 to 40°C (40 to 104°F)
Viscosity Limit	<50 cP
Power Requirement	100/230 VAC, 50/60 Hz
Maximum Power	67 W at 115/230 VAC
Dimensions	343 W X 337 D X 482 H mm (13.5 X 13.3 X 19.0 inches)
Weight	10.7 kg (23.6 lbs)
Sample Bottle Clearance	153 mm (6.02 inches)
Volume Accuracy	> 95%
Flow Rate Accuracy	> 95%
Sample Flow Rate	10 to 100 ml/min; Actual flow rate for the system is determined by the sensor's flow rate with step-by-step instructions and Pass/Fail results.
Tare Volumes for Probes	0.091 ml for 81 L X 1.2 ID mm (3.2 X 0.047 inches) 0.172 ml for 154 L X 1.2 ID mm (6.1 X 0.047 inches) 1.57 ml for 140 L X 6.35 ID mm (5.5 X 0.25 inches) - large bore

PharmSpec 3 Software

Processor	1.0 GHz or faster processor
Operating System	Windows 10 Enterprise 64-bit
Memory	2GB of RAM
Hard Disk	2 GB of available hard-disk space
Drives	USB port or network connection is required for installation
Display	1024 x 768 or higher resolution
Power Supply	Uninterrupted power supply (UPS) or network server
Removable Drive	Removable drive for backing up data, such as a recordable CD or a network server that can back up the computer hard drive
Printer	Color printer capable of printing at 300 dpi
USB Port	USB port to connect to the particle counting sensor
Software	Modern web browser and Microsoft® Excel®, Word® or Adobe® Acrobat® (to access PharmSpec reports)

Standard Sensors	**Range**
HRLD-150	1.3 µm to 150 µm
HRLD-150JA	1.3 µm to 150 µm (chemical compatibility)
HRLD-400	2 µm to 400 µm
HRLD-600JS	2 µm to 600 µm (chemical compatibility)
Compliance Certifications	CE Compliant per EMC and Low Voltage Directives Class 1 Laser Product Complies with IEC/EN 60825-1 and 21 CFR 1040.10 pursuant to Laser Notice 50 **
	** Contact manufacturer for complete compliance details

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PART-427SB08.14-A

MET ONE 3400+

Automate environmental monitoring for GMP cleanroom compliance with ONE easy decision

Our new MET ONE 3400+ Series Portable Airborne Particle Counter features automated integrated electronic SOPs and sampling maps that reduce training requirements—and sampling errors.

CHARACTERIZED
by ingenuity.

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It's all in the box

Customized Electronic SOP Maps

Using a web-browser interface, load your SOP map into the counter, mark sample locations, and define SOP requirements for each.

Interactive Tracking

Onscreen instructions help operators navigate your map and perform sampling according to the SOP. Location names turn green after sampling, making it easy to track progress at a glance. Managers can review daily monitoring progress including all sample results and alarms, via a web browser.

Automated SOP Version Control

To simplify SOP changes/updates, administrators use a web-based tool to approve each updated SOP via electronic signature. Changes are automatically replicated across all instruments.

Review and Approve

Supervisors can log-on to the instrument via a web-browser to review sampling results, alarms and comments and approve the final electronic record, attaching their electronic signature.

Secure Electronic Records

An electronic signature is attached to all approved final reports, which can then be exported in secure electronic format.

Barcode Function (optional)

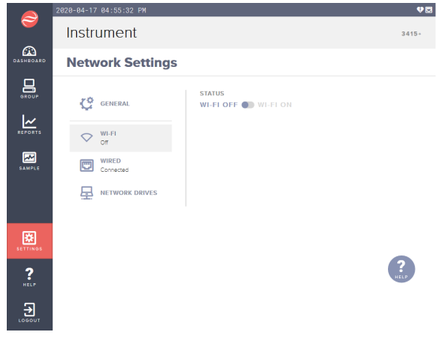
Connect a barcode reader to automatically capture sample location, production batch ID and more.

Plug-n-Play Networking

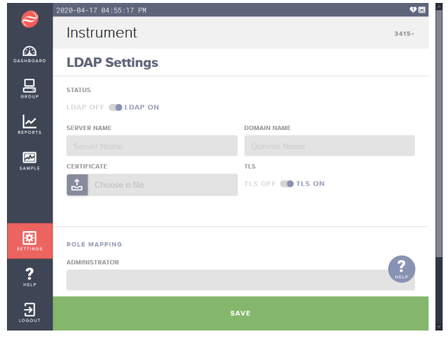
All instruments automatically create a network, which minimizes involvement of your IT department.

Sampling Options

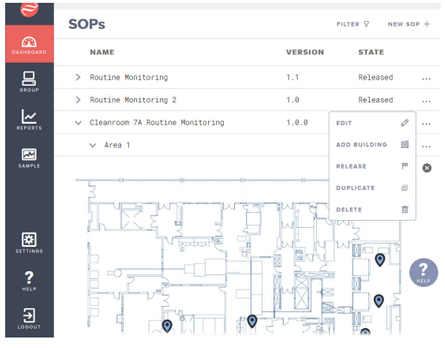
Available in 1 ft^3/min, 50 L/min and 100 L/min versions. The MET ONE 3400+ can sample 1m^3 in as little as 10 minutes



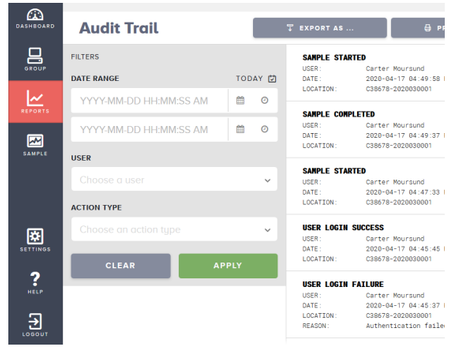
1. Configure network



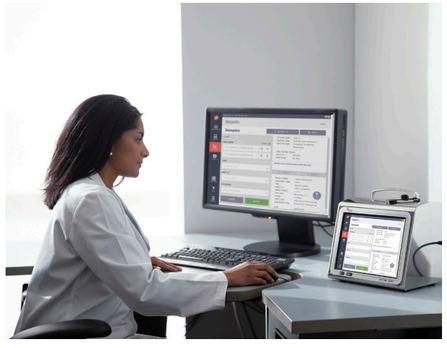
2. Choose LDAP settings including Active Directory



3. SOP version control inside the counter



4. Confirm all changes using built-in audit trail



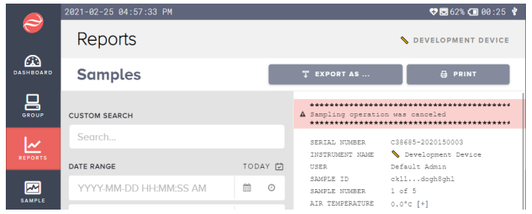
5. Review and approve monitoring results via web-browser

Simplified, secure data management eases audits

The MET ONE 3400+ helps you manage accurate cleanroom monitoring data via safe and secure internal software and web access—there's no external software needed. All data is encrypted, and users are never permitted to delete records.

And because it uses Microsoft Active Directory for Username and Password Control for log-on and electronic signatures, it supports 21 CFR Part 11 compliance and ALCOA guidance.

Attributable	Multi-level, Microsoft Active Directory Username and Password control creates unique electronic signatures for users
Legible records	Legible, secure PDF electronic record export for measurement results
Contemporaneously created	Secure PDF electronic records created in the counter - no manual data transcription or scanning of paper report
Original	Original electronic record created directly inside the counter
Accurate	Your SOPs and sampling maps uploaded into the counter with version control. Completed records reviewed and approved for accuracy in the counter remotely via web-browser. No manual counter configuration or sample location entry



To help you quickly locate data you need during an audit, you can use filters to review multiple parameters, including:

- Date
- User
- Location
- Failed logins
- Action type
- Alert level exceeded

Secure electronic records (Excel or PDF) can be exported directly to your network or to a USB device.

Each record contains:

- SOP version number
- User name
- Location name
- Time
- Date
- Alarms
- Counter configuration
- Sampling results
- Unlimited user defined fields, e.g. production batch ID, or room occupancy state, etc.

Designed for life in your cleanroom

Lighter to carry

At 12.4 lbs (5.6 kg)*, it's up to 26% lighter than earlier models.

Easier to use

Sensitive, 10-inch touchscreen enables reliable data entry even when users are double-gloved.

Optional barcode reader expedites data entry and minimizes potential for operator errors.

Quieter

New blower technology helps make the MET ONE 3400+ whisper quiet.

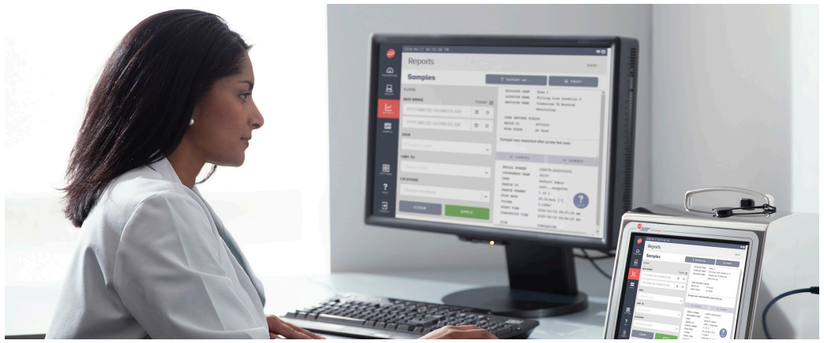
Easier to clean

Because it has a sealed touchscreen and stainless steel case, you can spray cleaners (VHP, bleach, alcohol) directly onto the instrument.

*Weight is without batteries

Networks so well so you don’t have to

We live in an interconnected world, but for many GMP regulated devices to share data requires huge software integrations and validation. The MET ONE 3400+ has built-in, secure networking capabilities that are validated out of the box using our IQ / OQ protocols. A lightweight networking protocol securely protected via transport layer security (TLS) in the MET ONE 3400+ interconnects multiple devices and shares configuration and sample data in a secure and compliant manner. Ease the burden on your IT department with the new MET ONE 3400+ air particle counter.



Identical web browser experience to instrument for SOP configuration, user management, or training through a projector.

An instrument can be installed into a remote location and fully controlled for sampling via the remote web interface, allowing for central control or remote operation in areas where technicians are not permitted.

Better networking features

Machine Groups and Data Replication	Each MET ONE 3400+ assigned to a machine group will share user configuration, SOP configuration, and sample data to enable any machine in the group to have a complete view of the environmental monitoring status. A light weight protocol connects the instruments to exchange true uniquely identified copies of data and to insure all instruments are in sync.
Wireless Connectivity	The MET ONE 3400+ includes an 802.11b/g wireless interface with full security capability, including enterprise grade 802.1x certificate-based authentication using WPA EAP (PEAP, TLS, and TTLS variants) and WPA2/PSK.
Network Shares	Within the MET ONE 3400+, Windows Network Shares can be configured to allow a technician to generate a report and upload it to that directory. Windows authentication controls rights and access to the share using tools already commonly deployed in most enterprises.
Audit Trail	A GMP grade audit trail is included in the instrument, including information on logins, logouts, power events, sampling, electronic signatures, SOP updates, and other critical actions taken on the instrument. Built in filtering and reporting simplifies review and approval of audit events.

Product specifications

MET ONE 3400+ Specifications

Particle Counting Performance	**MET ONE 3413+**	**MET ONE 3415+**	**MET ONE 3423+**	**MET ONE 3425+**	**MET ONE 3445+**
Standard Sizes	0.3, 0.5, 1.0, 3.0, 5.0, 10.0 µm	0.5, 1.0, 2.0, 3.0, 5.0, 10.0 µm	0.3, 0.5, 1.0, 3.0, 5.0, 10.0 µm	0.5, 1.0, 2.0, 3.0, 5.0, 10.0 µm	0.5, 1.0, 2.0, 3.0, 5.0, 10.0 µm
Flow Rate	28.3 LPM (1.0 CFM)	28.3 LPM (1.0 CFM)	50 LPM (1.77 CFM)	50 LPM (1.77 CFM)	100 LPM (3.53 CFM)
Flow Rate Tolerance	±5%				
Time to sample 1 m^3	35.3 minutes	35.3 minutes	20 minutes	20 minutes	10 minutes
Zero Count	1 count or less in 5 minutes, 95% confidence level				
Coincidence Loss	10% at 36,000,000 particles per m^3	10% at 36,000,000 particles per m^3	10% at 20,000,000 particles per m^3	10% at 20,000,000 particles per m^3	10% at 10,000,000 particles per m^3
Counting Efficiency - 50%	50% ±20% for 0.3 µm	50% ±20% for 0.5 µm	50% ±20% for 0.3 µm	50% ±20% for 0.5 µm	50% ±20% for 0.5 µm
Counting Efficiency - 100%	100% ±10% for 0.45 µm	100% ±10% for 0.75 µm	100% ±10% for 0.45 µm	100% ±10% for 0.75 µm	100% ±10% for 0.75 µm
Light Source	Long Life Laser™ diode with 10-year Mean Time To Failure				
Pump Type	Filtered to ISO 3 specifications, 3/8" NPT pipe fitting				
Exhaust	3/8" NPT pipe fitting available				
Physical and Electrical Specifications					
AC Power Supply	Output: 24 VDC, 5.0 A Maximum; Input: 80-264 VAC, 47-63 Hz, 1.2 A Maximum				
Battery Type and Quantity	1, 2 or 3 Li Ion Rechargeable Smart Battery Packs				3 Li Ion Recharge-able Smart Battery Packs
Battery Life (Continuous Sampling) w/ 1 Battery	3 hours	3 hours	3 hours	3 hours	Pump will not operate
Battery Life (Continuous Sampling) w/ 2 Battery	6.25 hours	6.25 hours	6.5 hours	6.5 hours	4 hours
Battery Life (Continuous Sampling) w/ 3 Battery	9.25 hours	9.25 hours	9.75 hours	9.75 hours	5.5 hours
Maximum Battery Recharge Time	3.5 hours (with 2 batteries)				6.75 hours (with 3 batteries)
Dimensions	26.7 cm W x 26 cm H x 21 cm D (10.5" W x 10.25" H x 8.25" D)				
Weight (without battery)	5.6 kg (12.4 lbs)				
Weight (with included batteries)	6.5 kg (14.3 lbs) with 2 batteries				6.9 kg (15.3 lbs)
Enclosure Material	316 Stainless Steel				
Operating Temperature and Humidity	0 to 40°C (32 to 104°F), 10 to 90% relative humidity, non-condensing				
Storage Temperature and Humidity	-20 to 50 degree C (-4 to 122 F), 0 to 98% relative humidity, non-condensing				
User Interface					
Screen	10" High Resolution LCD				
Interface	High sensitivity capacitive touch screen - works with dual gloves				
Alarms	Unlimited user defined alarms per channel or external environmental sensor				
Sampling Configuration Options	Sample by time or volume, up to 100 cycles, with user defined time intervals				
Electrical Interfaces					
USB Host	3 Type A USB 2.0 Host Ports				
USB Device	1 Type B USB Device Port				
Ethernet	1 802.3 Compliant 10/100 BASE-TX Auto negotiating with Auto MDI-X				
WiFi	802.11 b/g 2.4 GHz WiFi Radio				
Environmental Probe	Proprietary DIN port for Relative Humidity and Temperature sensor probe PN 2088373-01				

Ordering information

		Sample Flow Rate	Minimum Particle Size
C38675	APC, Port, MET ONE 3413+	28.3 LPM	0.3 µm
C38678	APC, Port, MET ONE 3415+	28.3 LPM	0.5 µm
C38681	APC, Port, MET ONE 3423+	50 LPM	0.3 µm
C38684	APC, Port, MET ONE 3425+	50 LPM	0.5 µm
C38687	APC, Port, MET ONE 3445+	100 LPM	0.5 µm

Each part number includes the instrument, 2 batteries, power supply, ISO probe and stand, 10 feet of tubing, and a cleaning brush. C38687 includes 3 batteries.

Part Number	Description
C64707	Probe, Isokinetic, SS, for 100 LPM
C64708	Probe, Isokinetic, SS, for 28.3 LPM
C64709	Probe, Isokinetic, SS, for 50 LPM
C64713	Tubing, Hytrel®, 3/8"ID, 1/2"OD (10' Long)
2088000-02	Filter Scan Probe, No Electronics. 28.3 LPM*
C64705	Paper, Thermal 58mm Wide Roll (Pack of 10)
2088373-01	Probe, Relative Humidity & Temperature
C64706	Battery. Power Supply, External 24VDC 3400+
C50400	Battery, 3400+
C64693	External Dual Battery Charger
C64408	Cordset, IEC Type I, Australia
C64410	Cordset, IEC Type N, Brazil
C64412	Cordset, IEC Type E, Europe
C64413	Cordset, IEC Type D, India
C64414	Cordset, IEC Type F, Korea
C64415	Cordset, IEC Type G, UK
2080732-13	High Pressure Diffuser, 28.3 LPM
2080732-12	High Pressure Diffuser, 50 or 100 LPM
C50352	Cap, I/O Connectors 3400+
C56591	Wheeled, Hard Sided Transit Case 3400+

*not available in EU

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