## APSS-2000

Automated Parenteral Sampling System

# Sizes and counts suspended particulate matter in a wide range of liquids to meet regulation standards 

Without measurement there is no control

The APSS-2000 syringe sampling system sizes and counts suspended particulate matter in a wide range of liquids and meets or exceeds all current USP, EP, and JP requirements. Recipe functions allow the APSS-2000 to adapt to future regulatory changes.
The APSS-2000 system consists of an SLS-2000 syringe sampler, a LiQuilaz ${ }^{\oplus}$ II E Series light obscuration spectrometer, and SamplerSight Pharma software, allowing reports to meet 21 CFR Part 11 regulations.

## BENEFITS

## Defect Reduction

- $100 \%$ sample volume for greater accuracy
- A precise sample volume within 0.4 ml is achieved with the syringe sampler, producing repeatable results
- SamplerSight Pharma software comes with a Validation Information Notebook, providing comprehensive software development documentation and full IQ, OQ , and PQ protocols
- SamplerSight Pharma complies with FDA 21 CFR 11


## User-Friendly

- Reduce operator error and ensure process accuracy with recipes for repeat sample processing to USP, EP, or JP standards
- Automated particle counter calibration wizard for full calibration or routine verification
- Alarm levels for pass/fail criteria ensure quality control
- Automated backup scheduling ensures enhanced data integrity


## Comprehensive System

- Easy-to-use pull-down menus
- Active Directory security password maintains system integrity
- Particle measurements are reported per ml or per container values
- Small sample volume minimizes waste of expensive product
- Various custom report formats are available
- Electronic report approval


## FEATURES

- Particle size capability from 1.5 to $125 \mu \mathrm{~m}$
- Fifteen user-selectable sizing channels
- Meets and exceeds all USP, EP and JP requirements
- Sample volumes from 0.4 ml to 1 liter
- Adapters for SVI and IV bag testing
- Automated sensor calibration
- Plug and play ultrasonic bath and magnetic stirrer options available


## APPLICATIONS

- Pharmaceutical parenteral monitoring to USP, EP, JP and FDA standards
- Parts/medical device cleanliness testing
- Laboratory water sampling
- Water for Injection (WFI) and Purified Water (PW) testing
- Filter efficiency testing


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| Liquid Sensor | LiQuilaz $^{\oplus}$ II E-20P | LiQuilaz ${ }^{\oplus}$ II E-15P |
| :--- | :--- | :--- |
| Size Range | $2-125 \mu \mathrm{~m}$ | $1.5-125 \mu \mathrm{~m}$ |
| Location | Internal to SLS-2000 |  |
| Size Channels | 15 |  |
| Flow Rates | $20 \mathrm{ml} / \mathrm{min}$ |  |
| Volume Sampled | $100 \%$ |  |
| Maximum Concentration | 10,000 per $\mathrm{ml}{ }^{1}$ |  |
| Sample Temperature | $50-122^{\circ} \mathrm{F}\left(10-50^{\circ} \mathrm{C}\right)$ |  |
| Zero-count Level | $<1$ count per 10 ml |  |
| Capillary Size | $0.5 \times 0.7 \mathrm{~mm}$ |  |
| Maximum Pressure | 25 psi |  |
| Maximum Sample Viscosity | 35 centipoise @ $20 \mathrm{ml} /$ min |  |
| Laser Source | Laser diode |  |
| Wetted Surface Materials | Fused Silica, Black Quartz, Teflon, Kel-- $\odot$, Kalrez ${ }^{\oplus}$ |  |

${ }^{1}$ Greater than $90 \%$ accuracy (less than $10 \%$ coincidence loss) at maximum recommended concentration.

| Liquid Sampler | SLS-2000 |
| :--- | :--- |
| Syringe Size | $1,5,10$, and $25 \mathrm{ml}(10 \mathrm{ml}$ is standard and included) |
| Sampling Mode | Vacuum |
| Minimum Sample Volume ${ }^{2}$ | $0.4 \mathrm{ml} @ 20 \mathrm{ml} / \mathrm{min}$ |
| Wetted Surface Materials | Glass, Teflon |
| Dimensions (H x W x L) | $17.1 \times 9 \times 15 \mathrm{in}(43.4 \times 22.9 \times 38.1 \mathrm{~cm})$ Including particle counter |
| Weight (Particle Counter) | $30 \mathrm{lb}(13.6 \mathrm{~kg})$ Including particle counter |
| Power | $100-240 \mathrm{~V}, 50-60 \mathrm{~Hz}$ |
| Environment Temperature | Temperature $50-86^{\circ} \mathrm{F}\left(10-30^{\circ} \mathrm{C}\right)$ |
| Humidity | $0-98 \%$ non-condensing |

${ }^{2}$ Minimum sample volume depends on the sample syringe used.

| Software | SamplerSight Pharma |
| :--- | :--- |
| Operating System | Windows $^{\circledR} 10$ |
| Developer | Particle Measuring Systems |
| Test Procedure | Software Validation Information Notebook |

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