# Performance Maintenance Protocol

# Sample Manager-Fixed Loop

(SM-FL, SM-FL PLUS, µSM-FL, Trap Valve Manager, Sample Manager, AutoSampler, and nanoACQUITY Sample Manager)

For ACQUITY UPLC<sup>®</sup> (IVD and non-IVD), I-Class (IVD and non-IVD), nanoACQUITY UPLC<sup>®</sup>, and M-Class Systems

| System name: | E10NPS733M  |
|--------------|-------------|
| PM date:     | 05-Oct-2020 |

# **Guidelines**

This performance maintenance (PM) protocol outlines maintenance tasks you should regularly perform on Waters systems. Regular maintenance ensures optimum performance and uninterrupted troublefree operation.

# Schedule

Waters recommends that performance maintenance visits be performed once a year. Systems under heavy use or using aggressive solvents need more frequent maintenance. For detailed maintenance schedules, refer to the appropriate user guide located on Waters.com. Failure to follow the maintenance schedules as described in the user guide might result in unreliable operation and inaccurate laboratory results.

# **Safety considerations**

Some protocols might involve removing instrument covers, exposing the performer to high voltages, high currents, and moving parts. This presents risks of electric shock or damage to the instrument. To reduce these risks, Waters recommends that these protocols be conducted by certified Waters field service engineers with access to the latest information on Waters products. Waters is not responsible for actions initiated by an unqualified performer. If you are unsure, have a Waters certified field service engineer conduct the performance maintenance activity.

# Waters Quality Parts

Waters designs and manufactures Waters Quality Parts<sup>®</sup> to the same strict regulatory standards it uses for its high-performance Waters systems. Waters recommends using Waters Quality Parts for all maintenance activities. Failure to use Waters Quality Parts might compromise laboratory results and reliability.

# **Customer education**

Waters offers courses on operating and maintaining its high-performance systems, as well as courses designed to help you maintain professional competency and further your knowledge in chromatography, mass spectrometry, and Waters data systems. For more information on available training courses, visit <u>Waters Educational Services</u> on Waters.com.

# **Qualification/compliance services**

Waters Compliance Services help you achieve and maintain the regulatory compliance of your LC and MS instruments and software with a combination of expertise, compliant-ready systems and software, and a portfolio of services to ensure that you consistently obtain quality data. To learn more, visit <u>Qualification/Compliance Services</u> on Waters.com.

# **PM task overview**

Tables 1, 2, and 3 are an overview of the PM tasks performed.

- **Note:** For instructions on performing these procedures, refer to the online Help or the appropriate user manual on Waters.com.
- **Note:** References to the BSM and SM-FL also pertain to the BSM PLUS and the SM-FL PLUS, respectively.
- **Note:** Calibration of the air sensor volume detection device is not required because it is not changed during performance maintenance.

### Table 1 – PM tasks (ACQUITY UPLC and I-Class)

| Inspect                                | Replace/rebuild                       | Verify                             |
|--|---------------------------------------|------------------------------------|
| Firmware version                       | Sample needle assembly                | Initialization diagnostics         |
| Fan                                    | Wash syringes                         | Calibrations and characterizations |
| Needle wash system                     | Sample syringe                        | Leak tests <sup>4</sup>            |
| Column heater/cooler or column manager | Injector valve cartridge <sup>1</sup> | Reset injection count              |
| Error logs                             | Sample loop <sup>1</sup>              |                                    |
|  | Needle-wash housing O-ring            |                                    |
|  | Tubing and fittings <sup>2</sup>      |                                    |
|  | Chassis air filter                    |                                    |

### Table 2 – PM tasks (nanoACQUITY)

| Inspect                                | Replace/rebuild                       | Verify                               |
|--|---------------------------------------|--------------------------------------|
| Firmware version                       | Sample needle assembly                | Initialization diagnostics           |
| Fan                                    | Wash syringes                         | Calibrations and characterizations   |
| Needle wash system                     | Sample syringe                        | Leak tests <sup>4</sup>              |
| Column heater/cooler or column manager | Injector valve cartridge <sup>1</sup> | Set pressure diagnostic <sup>5</sup> |
| Error logs                             | Sample loop <sup>1</sup>              | Reset injection count                |
|  | Needle-wash housing O-ring            |                                      |
|  | Chassis air filter                    |                                      |
|  | Trap valve cartridge <sup>3</sup>     |                                      |

### Table 3 – PM tasks (µSM-FL)

| Inspect                                | Replace/rebuild            | Verify                               |
|--|----------------------------|--------------------------------------|
| Firmware version                       | Sample needle assembly     | Initialization diagnostics           |
| Fan                                    | Wash syringes              | Calibrations and characterizations   |
| Needle wash system                     | Sample syringe             | Leak tests <sup>4</sup>              |
| Column heater/cooler or column manager | Needle-wash housing O-ring | Set pressure diagnostic <sup>5</sup> |
| Error logs                             | Chassis air filter         | Reset injection count                |

- $^1\,$  The injector valve cartridge and sample loop are not replaced as part of the  $\mu SM$ -FL performance maintenance.
- <sup>2</sup> From the sample manager to the column (ACQUITY UPLC only); and from the SM and SM-FL to the Binary Solvent Manager.
- <sup>3</sup> nanoACQUITY UPLC only.
- <sup>4</sup> For ACQUITY UPLC and I-Class (non-IVD/IVD), perform the dynamic leak test (system) when using ICS version 1.50 or higher.

For nanoACQUITY UPLC, perform the dynamic leak test (system) when using ICS version 1.30 or higher.

For the µSM-FL, perform the dynamic leak test (system).

When performing the dynamic leak test, choose **Column** as the End Point. Evaluate the fluid-handling integrity of the Binary Solvent Manager up to and including the inject valve of the sample manager (pin plug at port 6 of the inject valve).

 $^5$  nanoACQUITY UPLC and  $\mu SM\mbox{-}FL$  only.

# PM task descriptions

Performance maintenance consists of three task categories:

- Inspect
- Replace or rebuild parts
- Verify
- **Note:** If the instrument fails pre- or post-performance maintenance inspections or verifications, it might need additional service beyond the scope of this protocol. Such service might incur additional parts and labor charges.

# Inspect

- 1. If the instrument is off, power it on and allow it to complete software checks.
- 2. Inspect the firmware and, if appropriate, update it.
- 3. Ensure that the fan grate on the rear of the instrument is clear of debris and dust; clean if necessary.
- 4. Prime the needle wash and wash the needle.
- 5. Inspect the column trays for solvent residue and clean if necessary.
- 6. Review error logs for any errors and troubleshoot as necessary.

# **Replace or rebuild parts**

Using the parts in the PM kit, replace or rebuild parts as necessary.

**Note:** For instructions on replacing parts, see the appropriate user manual on Waters.com.

# Verify

After completing the maintenance tasks, verify instrument performance:

- 1. Power-on the instrument and allow it to complete on-board software checks.
- 2. Perform the calibrations and characterizations:
  - Calibrate the X, Y, and Zp axes (ACQUITY UPLC and nanoACQUITY UPLC only)
  - Calibrate R axis (I-Class and µSM-FL only)
  - Calibrate the rotary tray (I-Class and µSM-FL only)
  - Calibrate the needle *z*-axis
  - Characterize the needle seal
  - Characterize the needle and loop volumes
- 3. Perform the leak tests:
  - Sample syringe leak test
  - Wash syringe leak test
  - Needle seal leak test
  - Back-pressure regulator test
  - Dynamic leak test (refer to footnote 4 on page 4)

- 4. Perform the 'Set pressure diagnostic' (nanoACQUITY UPLC and  $\mu$ SM-FL only).
- 5. Record the current injection count, and then reset the injection count.

# **Results/checklist**

A Waters field service engineer completes the test results, checklist, and confirmation sections.

# **Test results**

| Table 2 – Firmware version  | 🛛 Yes 🗌 No 🗌   | N/A            |                |
|---|----------------|----------------|----------------|
| Firmware revision   | 1.42           |                |                |
| Firmware revision for Trap Valve<br>Manager (if applicable)             | n/a            |                |                |
| Table 3 – Calibrate X, Y, and Zp axes<br>(ACQUITY UPLC and nanoACQUITY) | 🛛 Yes 🗌 No 🗌   | N/A            |                |
| X offset (mm)   | ١              | ' offset (mm)  | Zp offset (mm) |
| 0.88  |                | -1.36          | 2.39           |
| Table 4 – Calibrate R axis<br>(I-Class and µSM-FL)                      | 🗌 Yes 🗌 No 🛛   | N/A            |                |
| R offset (mm)   |                |                |                |
| Table 5 – Calibrate rotary tray<br>(I-Class and µSM-FL)                 | 🗌 Yes 🗌 No 🔀   | N/A            |                |
| Offset (degrees)  |                |                |                |
| Table 6 – Calibrate needle z-axis                                       | 🛛 Yes 🗌 No 🗌   | N/A            |                |
| Z offset (mm)   | 3.69           |                |                |
| Table 7 – Characterize needle seal                                      | 🛛 Yes 🗌 No 🗌 🛛 | N/A            |                |
| Pass or fail  |                | Pressure (psi) | Offset (mm)    |
| 🛛 Pass 🗌 Fail   |                | 122            | 61.00          |

# Table 8 – Characterize needle and loop 🛛 Yes 🗌 No 🗌 N/A volume

| System volume with loop (µL) | System volume without loop (µL) | Loop (µL) | Needle (µL) |
|------------------------------|---------------------------------|-----------|-------------|
| 29.3                         | 23.6                            | 5.3       | 15.3        |

| Pass or fail  | Test     | Compressed | Decompressed | Start    | End      | Pressure | Average       |
|---------------|----------|------------|--------------|----------|----------|----------|---------------|
|               | pressure | volume     | volume       | pressure | pressure | change   | pressure leak |
|               | (psi)    | (µL)       | (µL)         | (psi)    | (psi)    | (psi)    | (psi/sec)     |
| 🛛 Pass 🗌 Fail | 150      | 2.0        | 0.9          | 152      | 114      | -37      | -2            |

### Table 9 – Sample syringe leak test

### Table 10 – Wash syringe leak test

# 🛛 Yes 🗌 No 🗌 N/A

🛛 Yes 🗌 No 🗌 N/A

| Syringe | Pass or fail  | Test<br>pressure<br>(psi) | Compressed<br>volume<br>(µL) | Decompressed<br>volume<br>(µL) | Start<br>pressure<br>(psi) | End<br>pressure<br>(psi) | Pressure<br>change<br>(psi) | Average<br>pressure<br>leak<br>(psi/sec) |
|---------|---------------|---------------------------|------------------------------|--------------------------------|----------------------------|--------------------------|-----------------------------|--|
| Weak    | 🛛 Pass 🗌 Fail | 190                       | 28.2                         | 28.0                           | 195                        | 183                      | -12                         | 0  |
| Strong  | 🛛 Pass 🗌 Fail | 190                       | 23.5                         | 24.0                           | 193                        | 178                      | -13                         | -1                                       |

### Table 11 – Needle seal leak test

### Yes 🗌 No 🗌 N/A

| Pass or fail  | Compressed<br>volume<br>(µL) | Decompressed<br>volume<br>(µL) | Start pressure<br>(psi) | End<br>pressure<br>(psi) | Pressure<br>change (psi) | Average<br>pressure leak<br>(psi/sec) |
|---------------|------------------------------|--------------------------------|-------------------------|--------------------------|--------------------------|---------------------------------------|
| 🛛 Pass 🗌 Fail | 45.1                         | 28.0                           | 120                     | 100                      | -19                      | -1                                    |

### Table 12 – Back-pressure regulator test 🛛 Yes 🗌 No 🗌 N/A

| Pass or fail  | Start pressure (psi) | End pressure (psi) | Average pressure (psi) | Standard deviation (psi) |
|---------------|----------------------|--------------------|------------------------|--------------------------|
| 🖾 Pass 🗌 Fail | 131                  | 127                | 127                    | 0                        |

### Table 13 – Dynamic leak test

### 🗌 Yes 🗌 No 🖂 N/A

(Firmware dependent)

|                               | End point column (choose one) | one) Leak rate |               |
|-------------------------------|-------------------------------|----------------|---------------|
| Inject valve Outlet of column |                               | (nL/min)       | Pass or fail  |
|                               |                               |                | 🗌 Pass 🔲 Fail |

#### 🛛 Yes 🗌 No 🗌 N/A Table 14 – Set pressure diagnostic (nanoACQUITY and µSM-FL)

| Solvent | Pre-sensor flow rate (µL/min)   | Post-sensor flow rate (µL/min) | Pass or fail  |  |  |  |
|---------|---|--------------------------------|---------------|--|--|--|
| A1      | 4.238   | 0.015                          | 🛛 Pass 🗌 Fail |  |  |  |
| B1      | 6.057   | 0.001                          | 🛛 Pass 🗌 Fail |  |  |  |
|         | A potential leak is indicated if the A1 solvent post-sensor flow rate is greater than 0.020 µL/min, or a difference between the pre-sensor and post-sensor flow rates is greater than 0.15 µL/min for the A1 and B1 solvents. |                                |               |  |  |  |

# Table 15 – Injection count

# 🖂 Yes 🗌 No 🗌 N/A

Injection count 442

# Checklist

Note: Select N/A if the task does not apply.

# Inspect

| All inspect tasks completed | Yes 🗌 No 🗌 N/A |
|-----------------------------|----------------|
|                             | Comments:      |

# Replace/Rebuild

| Sample needle assembly     | ⊠ Yes □ No □ N/A |
|----------------------------|------------------|
| Wash syringes              | ⊠ Yes □ No □ N/A |
| Sample syringe             | ∑ Yes □ No □ N/A |
| Injector valve cartridge   | ∑ Yes □ No □ N/A |
| Sample loop                | ∑ Yes □ No □ N/A |
| Needle wash housing O-ring | ∑ Yes □ No □ N/A |
| Tubing and fittings        | ⊠ Yes □ No □ N/A |
| Chassis air filter         | ⊠ Yes □ No □ N/A |
| Trap valve cartridge       | ⊠ Yes □ No □ N/A |
|                            | Comments:        |

# Verify

| All verify tasks completed | ∑ Yes □ No □ N/A |
|----------------------------|------------------|
|                            | Comments:        |