1. **Purpose**

This procedure provides instructions for evaluation of Ion PGM Sequencer instrument software updates to determine necessary actions to ensure the equipment functions according to established criteria to produce the quality of products and services required by the *“insert laboratory name here”*.

1. **Scope**

This document applies to Ion PGM Sequencer and related Ion instruments that are used within the *(Your Lab / Branch, etc.)* for DNA or RNA sequencing

1. **Related Documents**

|  |  |
| --- | --- |
| **Title** | **Document Control Number** |
| Ion PGM Sequencer Software Update Form |  |

1. **Responsibilities**

|  |  |
| --- | --- |
| **Position** | **Responsibility** |
| All laboratory staff | * Ensure software is properly updated according to established laboratory guidelines
* Follow documented software update process
 |
| Branch Chief / Team Lead | * Ensure documented procedures for the proper documentation of software updates are established
* Ensure documented procedures are followed
* Review and approves the Ion PGM System Software Update Form
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| Quality Manager | * Ensure documented software update procedures are available to the end user
* Review and approve the Ion PGM Sequencer Software Update Form
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1. **Procedure**
	1. Any updates to the equipment software require evaluation and approval prior to installation.
	2. Obtain the Ion PGM Sequencer Software Update Form and the Ion software release notes.
	3. ***Complete the Ion PGM Sequencer Software Update Form***
		1. Record the current and new software versions. Note: Indicate the TorrentSuite versions and attach a list of software versions for Ion PGM Sequencer components, as applicable.
		2. Identify the Ion-related instruments in use.
		3. Document the Ion PGM sequencing workflow(s) currently used in the laboratory.
		4. Indicate if any additional plug-ins or kits are downloaded.
		5. Review each bullet point in the software release notes and evaluate the following:
			1. Determine if the update affects the sequencing workflow used in the laboratory.
			2. Determine if the update potentially affects the sequencing data output results.
		6. Evaluate the action required to ensure the equipment functions as expected following the software updates:

| **Updates affect the sequencing workflow?** | **Updates potentially affect the sequencing data?** | **Required Action** |
| --- | --- | --- |
| No | No | None |
| Yes | No | None |
| Yes | Yes | Verification |
| No | Yes | Verification |

* + 1. Install the software updates as directed in the release notes.
			1. Ensure that the version of the current software components meets the update requirements. If the current version is older than what is required in the release notes for normal update, contact technical support to ensure a successful update.
			2. Use the same user account for both the Torrent Browser and instrument software updates.
		2. If verification is required, proceed to step g); otherwise proceed to step h).
		3. Complete a verification run as described below prior to releasing the equipment back into service.
			1. Using a standard, well-characterized sample previously ran in the laboratory, perform a sequencing run.
			2. If the sequencing data obtained with the new software versions are comparable to the data obtained with the prior software versions, no further action is needed.
			3. If the sequencing data obtained with the new software versions are not comparable to the data obtained with the prior software versions, conduct a revalidation of the assay.
		4. Attach additional information as needed (e.g. Release Notes documentation, Verification / Validation data) to the Ion PGM Sequencer Software Update Form.
		5. Sign, date, and obtain applicable reviews and approvals.
		6. After updating the Torrent server, ensure all Ion-related instruments such as the Ion PGM Sequencer, Ion Chef, Ion OneTouch 2, and Ion OneTouch ES instruments are also updated, as applicable.
1. **Revision History**

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| --- | --- | --- | --- |
| **Rev #** | **DCR #** | **Change Summary** | **Date** |
|  |  |  |  |

1. **Approval**

Reviewed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_