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## 1. Introduction: Description and Scope

*Reference section 8.1, Software Development Planning of the WISE procedure, #730002721 for guidance on providing information on specific software development and maintenance planning elements for the product.*

This document describes the Software Development Plan for the embedded software ("Firmware") for the instruments being developed for the Orion Project. The software development activities and workflow are governed by the guidance provided in the WISE procedure and is consistent with system design requirement inputs as reflected in the following table:

| Software System(s) | IVD<br>(Yes/No) | Safety Classification<br>(N/A, None, B, or C) | Development Level<br>(Standard, Architectural or Detailed) |
|--------------------|-----------------|-----------------------------------------------|------------------------------------------------------------|
| QSM                | No              | N/A                                           | Detailed                                                   |
| SM-FTN             | No              | N/A                                           | Detailed                                                   |
| TUV                | No              | N/A                                           | Detailed                                                   |
| CM                 | No              | N/A                                           | Detailed                                                   |

The Release Type for this project is a New Product Release.

## 2. Change History

| Version | Description of Change              |
|---------|------------------------------------|
| 00      | Initial release for SW team review |
|         |                                    |

## 3. References

| Document Number | Document Name                                                     |
|-----------------|-------------------------------------------------------------------|
| 730002721       | Waters Instrument Software Engineering Procedure                  |
| 730001286       | Waters Instrument Development Procedure                           |
| 730002734       | Change Request and Issue Tracking Procedure                       |
| 721016839       | Product Requirements Document                                     |
|                 | Technical File                                                    |
|                 | Traceability Matrix                                               |
| 721018499       | CPU 3000 Common Library Software Requirements Specification (SRS) |

|           |                                                                |
|-----------|----------------------------------------------------------------|
| 721018501 | Orion QSM-R Software Requirements Specification                |
| 721018500 | Orion Sample Manager FTN-R Software Requirements Specification |
| 721018502 | Orion Column Manager Software Requirements Specification       |
| 721018503 | Orion Tunable UV Detector Software Requirements Specification  |

#### 4. Abbreviations and Definitions

| Term                                                | Definition                             |
|-----------------------------------------------------|----------------------------------------|
| ICS                                                 | Instrument Control Software            |
| WIDP                                                | Waters Instrument Development Process  |
| WISE                                                | Waters Instrument Software Engineering |
| WPDP                                                | Waters Product Development Process     |
| <a href="#">Add/Remove/Modify rows as necessary</a> |                                        |

#### 5. Development Partners

No development partners

## 6. Organization and Responsibilities/Project Document Control

WPDP project approvals are configured in accordance with the WPDP Project Document Approvals Matrix (730001141) and/or Function Workflow practices. Project Team members and individuals allocated to approval responsibility are listed below.

Software responsibilities are listed below. See instrument-level Design & Development Plan, reference [document number](#), for overall project responsibilities.

| SOFTWARE PROJECT RESPONSIBILITIES  |                        |                          |
|------------------------------------|------------------------|--------------------------|
| Primary Project Responsibility     | Name(s)                | WIDP Role                |
| Project Manager                    | Brian Edwardson        | Project Management       |
| Product Marketing Manager          | Sukhdev Bangar         | Product Management       |
| Evaluation Project Manager         | Peter Bastek           | Evaluation               |
| Technical Communications Lead      | Veronika Skoromnik     | Technical Communications |
| Software Project Manager           | Steve Payne            | Software Engineering     |
| Embedded Software Project Manager  | Dan Grattan            | Software Engineering     |
| Software Engineer                  | Dave Lamborghini (QSM) | Software Engineering     |
| Software Engineer/Tech. Lead       | Dmitry Khavulya (QSM)  | Software Engineering     |
| Software Engineer                  | John Carneiro (QSM)    | Software Engineering     |
| Software Engineer/Tech. Lead       | Aaron Lebeau (SM)      | Software Engineering     |
| Software Engineer                  | Eric Williams (SM)     | Software Engineering     |
| Software Engineer /Tech. Lead      | Adil Baqhum (TUV)      | Software Engineering     |
| Software Engineer                  | Aneesh Chuttani (TUV)  | Software Engineering     |
| Software Engineer/Tech. Lead       | Miguel Soares (CM)     | Software Engineering     |
| Software Engineer                  | Bill Anderson          | Software Engineering     |
| Software Test Engineer             | Steve Kraft            | Software Engineering     |
| Software Test Engineer             | Lonzell Hall           | Software Engineering     |
| Software Test Engineer             | Sharmila Vairamani     | Software Engineering     |
| Evaluation Engineer (Verification) |                        | Evaluation               |
| Evaluation Engineer (Validation)   |                        | Evaluation               |

| SOFTWARE PROJECT RESPONSIBILITIES |         |            |
|-----------------------------------|---------|------------|
| Primary Project Responsibility    | Name(s) | WIDP Role  |
| Technical Product Manager         |         | Quality    |
| Quality Representative            |         | Quality    |
| Compliance Engineer               |         | Compliance |

Change management roles supporting [730002734](#) are listed below.

| Change Request and Issue Tracking Roles (supporting procedure 730002734) |                              |
|--------------------------------------------------------------------------|------------------------------|
| Roles                                                                    | Name/s or Project Role       |
| Engineering Lead                                                         | Jennifer/Steve/Dan ???       |
| Evaluation Lead                                                          | Peter Bastek (or delegate)   |
| Design Assurance Lead                                                    | John Surfus (or delegate)    |
| Product Owner                                                            | Sukhdev Bangar (or delegate) |
| SCR Assessor/s                                                           | Sukhdev Bangar (or delegate) |

## 7. Process Description

The following Function Workflow procedures will be used:

- Waters Instrument Development Procedure (730001286)
- Waters Instrument Software Engineering Procedure (730002721)

The following Change Management procedure will be used:

- Change Request and Issue Tracking Procedure (730002734)

The following process/procedure customizations will be made with corresponding justifications:

| Customization                                                                                                                                                                                                                                                 | Justification                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Section 8.4 of Waters Instrument Software Engineering Procedure (730002721) describes the procedure for writing software detailed designs. The procedure will be followed but embedded software written for the Orion instruments will use a custom template. | The template specified in the procedure, 7302725 is insufficient for the needs of the embedded firmware. The template located at <a href="#">LC Instrument Firmware Detailed Design Template</a> will be used. This template is a superset of the WISE template which has additional guidance and sections to be used by instrument embedded software engineers to adequately describe the software design. |

## 7.1. Methodology

No project specific methodologies.

## 8. Schedules and Plans

The Orion Embedded Software schedule is driven by 3 factors

- Software development activities; requirements, design, implementation, test
- Orion program schedule; dependencies on availability of requirements and feedback on software documents as required by PDP
- Pathfinder hardware schedule; dependencies on documentation and availability of units

Note that, to date, software development has NOT been blocked by dependencies on the program or the hardware. Rather they are stated here for completeness as such dependencies will be noted in software schedule.

This development effort encompasses 4 instruments plus a shared library. Each has its own work breakdown structure and schedule.

| Component      | Plan/WBS                  |
|----------------|---------------------------|
| QSM-R          | <b>Orion QSM-R WBS</b>    |
| SM-FTN-R       | <b>SM FTN-R WBS</b>       |
| TUV            | <b>TUV Detector WBS</b>   |
| Column Manager | <b>CHM WBS</b>            |
| Common Library | <b>Common Library WBS</b> |

## 8.1. Resources

The following hardware units are required for software development. Note that this encompasses units required by other software developers that are not part of the embedded development team.

| Subsystem       | SW Development                                                                                                                                                            |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Sample Manager  | 2 SW developers<br>1 Integration test development<br>1 Integration test operation (for running automated integration tests)<br>1 iSym software for integration<br>5 TOTAL |
| Solvent Manager | 3 SW developers<br>1 Integration test development<br>1 Integration test operation (for running automated integration tests)<br>1 iSym software for integration<br>6 TOTAL |
| Detector        | 2 SW developers<br>1 Integration test development<br>1 Integration test operation (for running automated integration tests)<br>1 iSym software for integration<br>5 TOTAL |
| Column Product  | 1 SW developer<br>1 Integration test development<br>1 Integration test operation (for running automated integration tests)<br>1 iSym software for integration<br>4 TOTAL  |
| UI/UX (kiosk)   | 4 instrument SW development teams<br>1 integration test development<br>1 Integration test operation (for running automated integration tests)<br>4 ???<br>10 TOTAL        |
| iSym            | 4 instrument SW development teams<br>1 integration test development<br>1 Integration test operation (for running automated integration tests)<br>4 ???<br>10 TOTAL        |

## 8.2. Milestones

Software milestones are listed below.

| MILESTONES                                    |               |             |                                                                                     |
|-----------------------------------------------|---------------|-------------|-------------------------------------------------------------------------------------|
| Milestone                                     | Forecast Date | Actual Date | Comments                                                                            |
| Feasibility Phase Complete                    |               | June 2019   | Based on actual phase exit                                                          |
| Design Control Begins                         |               | Oct. 2018   | Started with cancellation of Luna                                                   |
| Definition Phase Complete                     | Sep 2019      |             | As specified in "Milestone Plan" in <a href="#">Pathfinder Project Baseline</a>     |
| Development Phase Complete                    | Oct 2020      |             | As specified in "Milestone Plan" in <a href="#">Pathfinder Project Baseline</a>     |
| Implementation Freeze                         | August 2020   |             | Finger in the wind estimate that we need 2 months of freeze before dev complete     |
| Design Freeze                                 | February 2020 |             | Finger in the wind estimate that we need 6 months implementation time before freeze |
| Code Freeze                                   | August 2020   |             | Same as implementation freeze?                                                      |
| Product Verification Phase Complete           | February 2021 |             | As specified in "Milestone Plan" in <a href="#">Pathfinder Project Baseline</a>     |
| Design Transfer Complete                      |               |             |                                                                                     |
| Product Release                               | June 2021     |             | As specified in "Milestone Plan" in <a href="#">Pathfinder Project Baseline</a>     |
| Design Transfer and Validation Phase Complete | January 2022  |             | As specified in "Milestone Plan" in <a href="#">Pathfinder Project Baseline</a>     |

## 9. Design Reviews

| SOFTWARE DESIGN REVIEWS             |               |             |                                                                                                                                                                                            |
|-------------------------------------|---------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Review Name                         | Forecast Date | Actual Date | Comments                                                                                                                                                                                   |
| Definition Phase Review             | Sep. 2019     |             | Per WPDP, design input review suggested for definition phase. Review SRSS                                                                                                                  |
| Implementation/Design Freeze Review | Feb. 2020     |             | Per WPDP, design output review suggested for design freeze (review design documentation, not code),                                                                                        |
| Implementation Review               | Aug. 2020     |             | <ul style="list-style-type: none"><li>Review new or updated designs since design freeze review prior to implementation freeze</li><li>Review implementation prior to code freeze</li></ul> |
| Product Verification Review         |               |             | No plan unless required by project team                                                                                                                                                    |
| Code Freeze Review                  |               |             | No plan unless required by project team                                                                                                                                                    |
| Design Transfer Complete Review     |               |             | No plan unless required by project team                                                                                                                                                    |
| Product Release Review              |               |             | No plan unless required by project team                                                                                                                                                    |

### 9.1. Code Reviews

Code reviews are performed on an ongoing basis as code is implemented (feature or bugfix). Developers and reviews adhere to a process for coding and reviewing as described in [JIRA Issue Definition of Done Sequence](#) (DoD). A code review is triggered by a pull request. Note that acceptance criteria must be met prior to a pull request as described in the DoD. Reviews may comment on the implemented code and accept the or reject the code based on their review. The code is reviewed to ensure it meets the functional and quality requirements as described in the relevant Software Requirements Specification (SRS) and Software Detailed Design (SDD) specification. In addition, the code is reviewed for adherence to the following guidelines

- [Programming Guidelines](#)

- [Design Guidelines](#)

## 10. Phase Gates

A WPDP Phase Gate will take place at the end of each project phase of the product development. For this project they are available at “Milestone Plan” section of [Pathfinder Project Baseline](#).

### 10.1. WPDP Phase Software Deliverables

Software documentation deliverables will be produced according to section 8 of the Waters Instrument Software Engineering Procedure, 730002721. The following tables detail deliverables per phase

| Definition Phase                 |      |
|----------------------------------|------|
| Deliverable                      | Note |
| QSM SRS                          |      |
| SM FTN -R SRS                    |      |
| TUV SRS                          |      |
| CMH SRS                          |      |
| Common Library SRS               |      |
| Pathfinder Embedded Software SDP |      |

| Development Phase                                        |                                                                                                                                                                      |
|----------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Deliverable                                              | Note                                                                                                                                                                 |
| QSM Architecture Document                                |                                                                                                                                                                      |
| SM FTN -R Architecture Document                          |                                                                                                                                                                      |
| TUV Architecture Document                                |                                                                                                                                                                      |
| CMH Architecture Document                                |                                                                                                                                                                      |
| Common Library Architecture Document                     |                                                                                                                                                                      |
| Pathfinder Embedded Software Design Package              | Will essentially be a list of design specifications where there is roughly a 1-1 correspondence between JIRA stories and design documents                            |
| Pathfinder Embedded Software Unit Implementation Package | Will provide a report of all Jira items from the software requirements agreed to in the definition phase where the status of each item should be “In-Test” or Closed |
| Pathfinder Embedded Software System Integration Package  | Will provide report of Jira integration test items                                                                                                                   |

| Development Phase                        |                        |
|------------------------------------------|------------------------|
| Deliverable                              | Note                   |
| Software implementation freeze checklist | Use template 730002735 |

| Product Verification Phase     |                                                                                           |
|--------------------------------|-------------------------------------------------------------------------------------------|
| Deliverable                    | Note                                                                                      |
| Release Candidates             | Production software builds as needed for testing and iterative fixes of discovered issues |
| Software Code Freeze checklist | Code freeze checklist using template 730002736                                            |

| Design Transfer and Validation Phase |      |
|--------------------------------------|------|
| Deliverable                          | Note |
| Software Release Media               |      |
| Software Recreate Procedure          |      |

## 11. Success Criteria

The project shall deliver software that meets the compliance and quality requirements outlined within the process and procedures utilized. All expected deliverables shall be documented, produced and archived.

WPDP phase gates available at As specified in “Success Criteria” in [Pathfinder Project Baseline](#).

## 12. Project Costs

Project cost are captured in the [Pathfinder Project Baseline](#). Labor costs for the embedded software development are included in the section entitled “High level Resource Estimate (FTEs)” section of the baseline. Similarly, capital equipment costs for the embedded software effort are included in the section entitled “High level Non-Labour Budget (\$k)”. **NOTE:** The capitol plan only goes through Q4 of 2019. Additional units will be required during 2020 as new versions of the hardware become available.

## 13. Related Projects and Products (External Dependencies)

This SDP address only the software development effort for the pathfinder embedded software (i.e. firmware) for the instrument hardware. Portions of this development effort are tightly coupled to the iSym/ISCAP development effort. Although part of the same

development effort, the iSym software has its own development plan. The plans are separate since the code bases, resources, development environment and functional requirements are distinct and separate. The iSym serves as the system controller for Orion. Development of the control and status interactions and the messaging format between the instruments and iSym are being jointly development by the two teams.

## **14. Design Input Traceability**

Traceability will be tracked by Systems Engineering in the traceability matrix as noted in [Pathfinder Phase Report](#). Each of the SRSs referenced in section 3 will sight the specific requirements from the PRD to be implemented. Subsequent architectural and design packages will sight those requirements providing traceability from the PRD to specific design documents.

## **15. Project Risks**

The Risk Management plan is developed and maintained by Design Quality Assurance as noted in [Pathfinder Phase Report](#). Specific project risks are identified in the “Project Risks” section of the same report.

## **16. Product Risk Management**

The Risk Management plan is developed and maintained by Design Quality Assurance as noted in [Pathfinder Phase Report](#).

## 17. Development Tool Configurations

The SOFTWARE SYSTEM(S) will be developed using the following tools:

| DEVELOPMENT TOOLS                     |                                        |         |                      |
|---------------------------------------|----------------------------------------|---------|----------------------|
| Name (Vendor)                         | Type                                   | Version | Special Requirements |
| Git                                   | Source Control                         |         |                      |
| Bitbucket (Atlassian)                 | Browser Based Front End to Git         |         |                      |
| SourceTree (Atlassian)                | Desktop Front End to Git               |         |                      |
| Jira                                  | Requirement and Feature Tracking       |         |                      |
| Jira                                  | Anomaly Tracking                       |         |                      |
| Lauterbach PowerDebug                 | JTAG debugger                          |         |                      |
| Lauterbach TRACE32                    | IDE front end to Lauterbach PowerDebug |         |                      |
| Coverity                              | Static Analysis                        |         |                      |
| Bitbucket (Atlassian)                 | Code Review                            |         |                      |
| Altera Software Development Kit (SDK) | Compiler                               |         |                      |

## 18. Constraints, Regulations, Standards, and Codes

| Document Number | Document Name                                  |
|-----------------|------------------------------------------------|
| EN 62304        | Medical Device - Software Life Cycle Processes |

As noted in section 1, this project is NOT to develop IVD software, so no safety classification is necessary.

## 19. Regulatory Strategy

Regulatory Affairs will manage this strategy. As of the writing of this document, the regulatory strategy is unavailable and un-assigned.

## 20. Design Transfer Strategy

Project design transfer strategy is currently undefined. Software Engineering will assist Manufacturing Test Engineering in developing manufacturing test strategy. Specific plan is **TBD**.

## 21. Verification

The Evaluation Team [and/or Applications Group](#) will generate and execute the Verification Plan for this project. See [document reference](#).

Software verification and system testing will be performed by the integration test team. Unit tests and integration tests will be developed by that team in concert with the development team. Tests will be executed automatically when features are committed to source control and issues will be reported in Jira as necessary. See [JIRA Issue Definition of Done Sequence](#) for additional details.

### 21.1. Software SYSTEM Testing

Software SYSTEM testing is governed by section 8.6 of the Waters Instrument Software Engineering Procedure, 730002721.

## 22. Validation

The Evaluation Team will generate and execute the Validation Plan for this project. See document **TBD**.

## 23. Skills and Training

Existing Waters personnel will be assigned to this project based on their knowledge and experience of developing real-time embedded systems in C++. In addition, job descriptions for personnel to be hired into this program also stipulate the required skills and experience required for this project.

Training specific to this project will be provided as needed for the various tools and steps in the development process.

## 24. Product Build

Instrument software build is automated. Upon commitment to the development branch in Git, a bamboo build server will kick off a build of the software, and, upon successful completion of the build will run automated integration tests. Integration tests will be developed in concert with the software ass described in [JIRA Issue Definition of Done Sequence](#).

| BUILD AND INTEGRATION TOOLS                         |                            |         |                      |
|-----------------------------------------------------|----------------------------|---------|----------------------|
| Name (Vendor)                                       | Type                       | Version | Special Requirements |
| Bamboo (Atlassian)                                  | Build server               |         |                      |
| Cobra (open source)                                 | Integration Test Framework |         |                      |
| TBD (Vendor name)                                   |                            |         |                      |
| TBD (Vendor name)                                   |                            |         |                      |
| TBD (Vendor name)                                   |                            |         |                      |
| <a href="#">Add/Modify/Delete rows as necessary</a> |                            |         |                      |

### 24.1. Software Distribution Creation

Refer to document WAT000156MP, "Procedure to Create and Verify Software Media Masters".

## 25. Configuration Management

Software configuration management activities are governed by section 10 of the WISE Procedure ([730002721](#)).

## 26. Configuration Item Identification

*Identify Software Configuration Item types – Identify the software and documentation items in the project that are subject to change. Provide detailed information on how to identify each item to be controlled.*

| CONFIGURATION ITEMS |                                                                                                                                                   |
|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Item                | Configuration Control                                                                                                                             |
| Source Code         | Bitbucket (using Git as underlying repository) – Separations Embedded 3K Project repositories:<br><a href="#">Separations Embedded 3K Project</a> |
| Technical Files     | SAP - Binaries, Media                                                                                                                             |
| Change Records      | JIRA Production Database                                                                                                                          |
| Documents           | Confluence and SAP                                                                                                                                |
| Software Artifacts  | Artifactory: http://rdeidgart:8081/artifactory/webapp/#!/home                                                                                     |

### **26.1. Activities and Tasks**

N/A

### **26.2. Configuration Control Entry**

A Software Item comes under configuration control when an SCR (Jira Story item) has been implemented and accepted for integration and that SCR has been closed but not verified. See Change Request and Issue Tracking Procedure ([730002734](#)) section 8 for workflow of SCRs.

### **26.3. Software Problem Resolution**

Problem resolution with a Software Item under configuration management is initiated with a Defect SCR (Jira bugfix item). See Change Request and Issue Tracking Procedure ([730002734](#)) section 8 for workflow and activity details of defect SCRs.

## 27. Product Release

The following are required to approve the Product Release Certificate for this product.

| PRODUCT RELEASE APPROVERS |                                       |
|---------------------------|---------------------------------------|
| Name                      | Title                                 |
| Richard Brody             | Senior Director, Software Development |
| Tatyana Friedman          | Senior Director, Systems Evaluation   |
| John Surfus               | Manager, Design Assurance             |

### 27.1. Release Notification

The following will be notified of product release, via a communication directly following the release.

| PRODUCT RELEASE NOTIFICATIONS |                                     |
|-------------------------------|-------------------------------------|
| Name                          | Title                               |
| Lisa Sacco                    | Senior Commercialization Specialist |
| Jaaffar Ismail                | Test Engineering                    |
| Janice Arsenault              | GSS                                 |