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## 1 Introduction

First Install (FI), formerly known as First of Kind (FoK), is an optional process, governed by the Launch [0316-01-P] and Service Readiness [0318-01-P] processes, that provides a time-controlled method to test the service delivery and/or order fulfillment readiness, and comprises of installation of PRODUCTS at a limited number of sites just after RfD gate, as set forth in the PDLM process [0330-01-P]. With a First Install, the SERVICE READINESS TEAM monitors first deployments of the software version to a specific subset of customers, in order to prepare for volume delivery. Reasons for First Install implementations:

- To evaluate accuracy and completeness of commercial order fulfillment systems
- To evaluate accuracy, completeness and usefulness of delivery and implementation procedures.

Note: If RfD and RC gates are merged, then First Installs may be performed at RC

First Install (FI) represent the first few deployments of new or revised PRODUCTS in customer site(s) which both the Organization and SERVICE ORGANIZATION monitor closely. Both organizations collaborate to address any PRODUCT, process or PRODUCT issues that is observed. All customer feedback is handled via standard procedures, and tools as set forth in the Complaint Handling procedure [0602-01-P] and Escalation Handling [0601-01-W4] work instruction. All PRODUCT related issues shall be handled via standard methods and tools as set forth in the Design Change [0339-02-P] and Defect Management [0339-01-P] procedures. All feedback and/or issues raised during FI shall be documents as part of the FI report.

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The Launch Team decides during the project whether to recognize First Install candidate customers. After RfD gate, the Launched PRODUCT may be monitored for early feedbacks out of First Installs, or for any PRODUCT issues and address them adequately. In case of a First Install, the local teams (e.g. Application Consultancy, Technical Consultancy & Project Manager) will be trained on the (new) PRODUCT functionality. The output of these training sessions may be used to update training program. If RfD has FI implementations, then the RC milestone can only occur after all FI implementations have been successfully conducted.

Optionally, First Install orders, including entitled upgrades covered under service contracts, may be processed, according to established practices, to verify order fulfillment readiness. The SRT monitors the First Install implementations to ensure their service deliverables are accurate and complete.

FI process can only be exercised on released PRODUCTS and does not provide any relief from the Release for Delivery Process [0314-01-P], and prior requirements that should be completed prior to release. FI is not a substitute for verification or validation activities.

This guidance provides the minimum requirements for First Install planning, execution and reporting.

## 2 Responsibilities

Role	Responsibilities
Clinical Application Specialist	Clinical assessment of issues, supports defining acceptable solutions.
Clinical Education Manager (SERVICE ORGANIZATION)	Responsible to the deployment of knowledge sharing among the different markets, based on the organizations guidance.
Product Support Engineer	<ul style="list-style-type: none"> <li>Responsible for the definition and implementation tracking of serviceability function within the product.</li> <li>Coordinates all service readiness deliverables, chairs FI, escalates as needed to Program and own management.</li> </ul>
Product Manager	Support customer communication, determines issues priority to address per FI team's feedback.
Program Manager	Coordinates all program cross-functional activities, ensures all critical issues identified are resolved, and escalates to the organization's Management.
Service Readiness Team (SRT)	<ul style="list-style-type: none"> <li>Responsible to follow-up on the applicable FI activities.</li> <li>Monitors the First Install implementations to ensure their service deliverables are accurate and complete.</li> </ul>
SW Architect	Updates/creates specifications and instructions, provides content to training, issues investigation and resolution.
Site's Service Project Manager (SERVICE ORGANIZATION)	Owens Customer communication, FI planning per site, manages site's implementation, provides progress status.
Technical Writer	Responsible for the creation of IFU based on R&D and SERVICE ORGANIZATION Engineers inputs.
Training lead (SERVICE ORGANIZATION)	Responsible for the training readiness and plans. Addresses any training issue from FI.

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**First Install**



## 3 Definitions and Acronyms

### 3.1 Definitions

Term	Definition
PRODUCT	In this guidance, refers to any Product Launch, Bundled Launch, Solution, Sub system, or Tool to be deployed for customers or service use
SERVICE ORGANIZATION	The entity to which the organization has subcontracted the responsibility for delivering the implementation, training and support services for the PRODUCT. This can be another Philips entity (e.g. SCS) or a third-party service provider.
SERVICE READINESS TEAM	The Product Support Engineer assembles and chairs the Service Readiness Team (SRT). The cross-functional SRT members are typically representatives from the Core team (e.g. Project Manager, Development and Application/Clinical Science, as defined in the Design and Development planning) and from the SERVICE ORGANIZATION (representing e.g. Deployment, Support, Training and Marketing) For minor releases, the SRT may be part of the Launch Team.

### 3.2 Acronyms

Short	Long
CE	Compute Environment
CSM	Customer Success Manager
CSP	Customer Service Plan
CSPP	Customer Support Product Plan
CTC	Clinical Transformation Consultant
FI	First Install
FoK	First of Kind
HW	Hardware
IDM	Intelligent Device Manager
IfU	Instruction for Use
IMS	Incident Management System
PA	Performance Assurance
PO	Purchase Order
RfD	Release for Delivery
SOW	Statement Of Work
SRT	Service Readiness Team
SW	Software
TC	Technical Consultant
UAT	User Acceptance Test
VCE	Virtual Compute Environment



## 4 Guidance

### 4.1 First Install Planning

#### 4.1.1 First Install criteria

**Entry criteria:** to successfully launch first install, the following condition(s) must be fulfilled:

- Site selection completed per the Launch process
- PRODUCT and/or components are released for delivery per NOR-D
- PRODUCT Deployed to the relevant deployment tool (IDM/Incenter)
- PRODUCT Documentation uploaded to the relevant deployment tool (DropZone/Incenter)
- PRODUCT assets set in IMS tools (OneEMS/Service Max)
- FI support team training completed
- Site Assessment completed as defined by PRODUCT pre-requisites
- Site Statement of Work

**Exit criteria:** to successfully complete monitoring period of first install, the following condition(s) must be fulfilled:

- SERVICE ORGANIZATION is able to deploy the solution without any engineering support.
- SERVICE ORGANIZATION escalation process implemented for new PRODUCT release.
- All issues determined as “must fix” must be resolved or have an acceptable workaround provided by Engineering.
- Train SERVICE ORGANIZATION teams that are tasked with supporting the first installations from the funnel.
- FI site updated with the new software version (Release Closed version), if applicable.
- Order fulfilment readiness is adequate (Optional).

Note: any additional criteria provided by the organization to the FI, will be documented in the FI plan and report.

### 4.2 First Install team

The details of the First Install team members and other resources will be documented as part of the FI plan. The following members meet regularly to receive and address the FI monitoring feedback:

- Service Readiness representative
- Program Manager
- R&D representative
- Clinical representative
- Product Manager
- Training representative
- Site's Service Project Manager

Additional team members can be added to the FI team, if needed.

### 4.3 First Install Site(s) List

Sites that are in-scope for First Install will be documented in the FI plan and report, including both site details such as: Region, Country, Site ID, Address and Site's main contact, as well as Philips contact details which related to the site, as follows:

- Philips Site's Project Manager
- Customer Success Manager (CSM)

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- Build lead
- Technical Consultant (TC)
- Application Consultant
- L0 Monitoring
- L1 lead
- L2 Clinical (SERVICE ORGANIZATION)
- L2 Technical Team (SERVICE ORGANIZATION)
- Database Administration
- Application Management
- Virtual Compute Environment (VCE)
- Infrastructure Management
- HL7 integration engineer
- Network Consultant
- Clinical Transformation Consultant (CTC)

### 4.4 Deployment Plan

The service project manager develops specific deployment plan for their site, which should reflect the major milestones as below:

- Project Start date
- Customer environment survey
- Customer SOW sign off date
- HW PO approval date (only if HW is needed)
- HW arrival on site date (only if HW is needed)
- Customer Training date
- Test Environment Build date
- Test Environment Install date
- Execute PA on Test Environment
- Customer UAT Start
- Customer UAT Finish
- Production Environment build date
- Production Environment install date
- Execute PA on Production Environment
- Installed Product
- Recent installed version

Each milestone will be monitored for its actual completion date, which will be documented in the FI report.

### 4.5 During First Install

#### 4.5.1 Issue handling and resolution

- The Site's Service Project Manager collects all the issues reported and ensures that service tickets are timely opened in the defined IMS tools per the applicable process (Complaint Handling [0602-01-P], and the Escalation Handling [0601-01-W4]).
- The Site's Service Project manager, or a delegate, follows up on issues escalated into Defects and are managed through the Defect Management procedure [0339-01-P].
- Any fixes applied to the site are of released versions which undergone the Design Change [0339-02-P] and the Release for Delivery [0314-01-P] procedures.



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### 4.5.2 Monitoring and Control

- Meeting Cadence: First Install team meet regularly daily/weekly, or per frequency determined by the team.
- Agenda:
  - First Install Status.
  - Review and clarify all issues.
  - Prioritize resolution timing for the issues.
  - Provide quick feedback on status of resolution of issues.
  - Action items.
- Offline work should be driven by the Program Manager based on the issues reported.

### 4.5.3 Communication with the Customer site

The Service Project Manager and/or Customer Success Manager will serve as the single point of contact with the customer. Any notifications, inquiries or requests made to the customer, should be sent through this point of contact.

### 4.5.4 Communication with the Business stakeholders

Program Manager provides regular updates to the stakeholders, highlighting and issues that need attention.

## 4.6 Summary and Conclusion

Summary of the First Install, any issues observed during first install, any changes such as SW releases or fixes deployed during the FI, as well as whether the PRODUCT has passed /failed the exit criteria via First Install monitoring, will be documented in the First Install report with their associated IDs (OneEMS ticket, Defect No.).

In case the PRODUCT failed to meet exit criteria, the pending issues that must be addressed will be documented in the First Install report.

PRODUCT documentation as well training material shall be updated by the Technical Writer per the conclusion and outcome of the FI, if needed.

## 4.7 FI Measurement

First Install timeliness (e.g. build, installation) is measured and compared to the CSPP timelines, the results will be documented in the First Install report. Any additional measured indicator or KPIs that was set as part of the First Install plan will be documented in the First Install report, as well.

## 5 References

Reference Number	Description
0314-01-P	Release for Delivery Procedure
0314-01-W2	Deployment via InCenter Work Instruction
0314-01-W3	Deployment via DropZone Work Instruction
0316-01-P	Launch Procedure
0318-01-P	Service Readiness Procedure
0318-02-P	Creation of Service Documentation Procedure
0330-01-P	Product Development Launch & Maintenance Procedure



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Reference Number	Description
0339-01-P	Defect Management Procedure
0339-02-P	Design Change Procedure
0601-01-W4	Escalation Handling Work Instruction
0602-01-P	Compliant Handling Procedure
0730-02-P	General Document Control Procedure

6 Document History

Revision	Description of changes
1.0	Initial Release

7 Document Control

Process	Owner(s)
Approval	Q&R Manager Operations Manager
Review	Product Support Engineer
Author	Moshe Elmaliach
Approval date	See eDMS
Effective date plan	Standard

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