

# SOP Deployment

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## 1. General Information

This SOP describes how we support the initial integration and update of integrations of our medical devices into the IT systems of our customers. Furthermore, it covers user management and user training. By following this process, we want to make sure that our customers receive our medical devices or services the intended way.

<b>Process Owner</b>	<i>&lt;enter role of process owner&gt;</i>
<b>Key Performance Indicators</b>	<i>&lt;enter KPIs to be tracked for the Management Review&gt;</i>

### Relevant other documentation:

- Integration Evaluation Checklist (IECL)
- Integration Validation Checklist (IVCL)
- Software Requirement Specifications
- List of Medical Devices (PROD)
- User Training Strategy

### 1.1. Integration Specifications

Integration Specifications are the technical requirements defined in the instructions for use as part of the technical documentation of medical devices.

## 1.2. Integration Checklists

The Integration Specifications are used to compile the Integration Evaluation Checklist. It is ensured that we do not offer medical devices or services which cannot be delivered by filling out this checklist, for which the Operations Team Representative is responsible. We fill out the Integration Validation Checklist after concluding integration work in order to validate if all technical requirements for successful integration have been completed.

## 1.3. Device Traceability

The operations team ensures that only released device versions are deployed to the customer environment. Deployment of device versions is documented as part of the medical device list. This file must contain at minimum:

- Use description (e.g. clinical use, test, etc.)
- Device description (e.g. device version, UDI, release date, identification number of the NB acc. to CE certificate)
- Company and contact data to a responsible person, deployment location

## 1.4. Project Management Tool

Optional:

<enter name> is used as the project management tool to coordinate integration work.

## 2. Process Overview

### 2.1. Evaluation of Integration Requirements per Customer

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### 2.2. Integration Coordination

### 2.3. Algorithm Deployment and Configuration

### 2.4. User Administration

### 2.5. User Training

## 2.6. Handling of Feedback

In case the operations team receives feedback (questions, complaints, praise, etc.) regarding the organization's medical devices and services, it proceeds as outlined in the SOP feedback management.

## 2.7. Handling of Updates

# Glossary

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Bar

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