VAL-XXXXX

Predetermined Change Control Plan Template

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# Introduction

## Purpose

This document serves as the Predetermined Change Control Plan (PCCP) for Medical Device Name developed by Name of Organization. This document describes the modifications that will be made to the Machine Learning Device Software Function (ML-DSF) for Medical Device Name and how the modifications will be controlled. This PCCP shall be included and discussed in General Device Characteristics of the marketing submission and included as a standalone section as a “Predetermined Change Control Plan”.

## Related Materials

|  |  |
| --- | --- |
| Document | Title Source standard |
| POL-0001 | Quality Manual *per ISO 13485* |
| SOP-001 | Data Management Operations *per Good Machine Learning Practices* |
| SOP-002 | Software and Algorithm Lifecycle Processes *per IEC 62304* |
| SOP-003 | Verification and Validation *per IEC 62304* |
| SOP-004 | Risk Management *per ISO 14971* |
| WOR-001 | Re-training DNN Models |
| PLAN-001 | Data Specifications *per Good Machine Learning Practices* |
| ARC-XXXX | Software Architecture Description *per IEC 62304* |
| SDS-XXXX | Software Design Specification and Detailed design *per IEC 62304* |
| REQ-003 | Core Module Performance requirements *per IEC 62304* |
| VVP-001 | Core Algorithm V&V protocol |
| RRR-001 | Re-training Report |
| PLAN-001 | Cloud deployment and monitoring |
| LBL-001 | User labeling and field notifications |

# Machine Learning Device Software Functions

The Medical Device Name software system is composed of several units, including units with Machine Learning Device Software Functions (ML-DSFs). See ARC-XXXX for further details.

[Insert an architecture diagram that describes the ML-DSF in context with the rest of the device design.]

The ML-DSF units undergoing modification directly impact the intended use of the product. This plan shall control such changes to ensure the device maintains original device planned performance.

The following planned device modifications described have been reviewed as changes which would otherwise require a new submission per *Deciding When to Submit a 510(k) for a Software Change to an Existing Device (FDA, October 2017)*.

# Description of Modifications

The ML-DSF incorporated into the wearable device system can predict and diagnose healthcare conditions by comparing the user’s Real-world EKG sensor data with personalized health (physiological) data. The ML-DSF core EKG algorithm “off-the shelf” is trained on representative sample data which can be updated through cloud-deployed changes. See SDS-XXXX for further details.

For the modification, consider:

* Is the modification described specific?
* Can the modification be verified and validated?
* Is the modification implemented automatically or manually?
* Will the modification be implemented across all devices on the market or locally?
* Are the modifications appropriate for a PCCP?
  + Does the modification improve the safety or effectiveness of the device?
  + Is the modification related to quantitative measures of ML-DSF performance specifications?
  + Is the modification related to device inputs of the ML-DSF?
  + Is the modification related to the device’s use and performance within a specific subpopulation?
* Is the modification in alignment with the intended use of the device?

### Modification #1 - Weekly Core Algorithm Re-training

The device contains a core ML-enabled algorithm for assessing a user’s healthcare state using ECG data and personal health history. This machine learning model is trained on sample data which may drift from population data over time. The modification proposed would be no change to the overall architecture or functionality, but instead re-training of the machine learning model using more recently acquired data to maintain the same level of performance over time. This core algorithm change can be deployed remotely and updated weekly. This is a change in quantitative measures of ML-DSF performance specifications…

### Modification #2 - Core Algorithm Retraining

This modification leverages real world data from new sources to improve the level of performance. This is considered a change in quantitative measures of ML-DSF performance specifications…

### Modification #3 - Core Algorithm Re-training

Real world data shows that current ML-DSF needs architecture modifications to account for new sources of data relevant to the training process.

# Modification Protocol

A comprehensive and lifecycle approach to ML-DSF modification shall be used to ensure the continued safety and effectiveness of the Medical Device Name software system. All changes are subject to quality system processes outlined in POL-0001 Quality Manual (ISO 13485) and software processes described in SOP-002 Software and Algorithm Lifecycle Processes (IEC 62304).

See [Appendix A from the FDA’s PCCP ML-DSF](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial) Guidance for example questions that may be considered to develop the Modification Protocol Section.

## Data Management Practices

* + 1. Method A

SOP-001 Data Management Operations describes how data shall be collected, synthesized, controlled, quality controlled and assured, labeled, enhanced, cleaned and sequestered. PLAN-001 Data Specifications Wearable Personalization describes the specific data requirements suitable for this modification to be met.

[Collection Protocols, Assurance of Data Quality, Reference Standard Determination, Sequestration of Test Data Sets]

* + 1. Method B

[Overview of Method B and associated supporting documents]

[Collection Protocols, Assurance of Data Quality, Reference Standard Determination, Sequestration of Test Data Sets]

## Re-Training Practices

* + 1. Method C

SOP-002 Software and Algorithm Lifecycle Processes (IEC 62304) describes how algorithm re-training is controlled and monitored. For this specific machine learning model WOR-001 Re-training DNN Models shall be used and a re-training report shall be produced per the instruction. This report identifies the training objectives, focus, implementation details and overall results of the activity including anomalies. RRR-001 Re-training Report documents the most recent re-training of the machine learning model. All anomalies are managed per the software problem resolution process described in SOP-002 Software and Algorithm Lifecycle Processes (IEC 62304). A new report shall be issued for each re-training activity.

[Discuss Re-training Objectives and Focus, Re-training Implementation]

* + 1. Method D

[Overview of Method D and associated supporting documents]

[Discuss Re-training Objectives and Focus, Re-training Implementation]

## Performance Evaluation

* + 1. Method E

The core algorithm shall undergo performance evaluation as part of any new product introduction (NPI) cycle. Any change to the software, whether it is anticipated to directly or indirectly affect the core algorithm performance, shall undergo performance testing per VVP-001 Core Algorithm V&V protocol. The performance requirements and assessment metrics are documented in REQ-003 Core Module Performance requirements.

[Triggers to Initiate Performance Evaluation, Assessment Metrics and Elements, Statistical Analysis Plans, Performance Targets, Additional Testing Needs]

* + 1. Method F

[Overview of Method F and associated supporting documents]

[Triggers to Initiate Performance Evaluation, Assessment Metrics and Elements, Statistical Analysis Plans, Performance Targets, Additional Testing Needs]

## Update Procedures

* + 1. Method G

The Medical Device Name software system shall undergo

field changes per the process outlined in PLAN-001 Cloud deployment and monitoring at least once per month if an approved build candidate is available. This process requires that users are notified per LBL-001 User labeling and field notifications. All approved build candidates are required to undergo software verification and validation per SOP-003 Verification and Validation.

[Software Verification and Validation, When and How Updates will be Implemented, Communication and Transparency to Users, Device Monitoring Plan, Marketing considerations]

* + 1. Method H

[Overview of Method H and associated supporting documents]

[Software Verification and Validation, When and How Updates will be Implemented, Communication and Transparency to Users, Device Monitoring Plan, Marketing considerations]

Table 1 - Modification to Modification Protocol Component Traceability

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Modification Protocol Component | | | |
| Modification | Data Management Practices | Re-training Practices | Performance Evaluation | Update Procedures |
| Modification #1 - Core Algorithm Re-training | SOP-001 DataOps  PLAN-001 Data Specifications Wearable Personalization  Method A  (See Section 4.1.1) | SOP-002 Software and Algorithm Lifecycle Processes (IEC 62304)  WOR-001 Re-training DNN Models  RRR-001 Re-training Report  Method C  (See Section 4.2.1) | REQ-003 Core Performance requirements  VVP-001 Core Algorithm V&V protocol  Method E  (See Section 4.3.1) | SOP-003 Verification and Validation  PLAN-001 Cloud deployment and monitoring  LBL-001 User labeling and field notifications  Method G  (See Section 4.4.1) |
| Modification #2 | Method B (See Section 4.1.2) | Method D (See Section 4.2.2) | Method F (See Section 4.3.2) | Method H (See Section 4.4.2) |
| Modification #3 | Method B (See Section 4.1.2) | Method D (See Section 4.2.2) | Method F (See Section 4.3.2) | Method G (See Section 4.4.1) |

# Impact Assessment

The impact of each change, as well as their collective impacts, are assessed using the risk management process described in SOP-004 Risk Management (ISO 14971).

The Impact Assessment for each modification should address the following questions:

* How does the version of the device with each modification implemented compare to the version of the device without any modifications implemented?
* What are the benefits and risks, including risks of social harm, associated with each individual modification?
* How do the activities proposed within the Modification Protocol continue to reasonably ensure the safety and effectiveness of the device?

For marketing submissions:

* How does the implementation of one modification impact the implementation of another?
  + How does the individual modification impact other device software functions, as well as device hardware?

If the ML-DSF is a multiple function device product

* Determine if additional information is necessary for submission per [Multiple Function Device Products: Policy and Considerations](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/multiple-function-device-products-policy-and-considerations).

#### Modification #1 Impact - Core Algorithm Re-training

[Discussion of the clinical benefits of this modification]

[Discussion of the risks associated with this modification, See ISO 14971:2019 Cl. 5.1-5.5, 6.0]

[Discussion of the risk mitigations, with references to specific risk management file artifacts and requirements, See ISO 14971:2019 Cl. 7.1-7.2, 7.5-7.6]

[Discussion of the overall impact on the medical device system, residual risk and labeling considerations, See ISO 14971:2019 Cl. 7.3, 7.4, 8.0]

#### Modification #2 Impact - Core Algorithm Re-training

[Discussion of the clinical benefits of this modification]

[Discussion of the risks associated with this modification, See ISO 14971:2019 Cl. 5.1-5.5, 6.0]

[Discussion of the risk mitigations, with references to specific risk management file artifacts and requirements, See ISO 14971:2019 Cl. 7.1-7.2, 7.5-7.6]

[Discussion of the overall impact on the medical device system, residual risk and labeling considerations, See ISO 14971:2019 Cl. 7.3, 7.4, 8.0]

#### Modification #3 Impact - Core Algorithm Re-training

[Discussion of the clinical benefits of this modification]

[Discussion of the risks associated with this modification, See ISO 14971:2019 Cl. 5.1-5.5, 6.0]

[Discussion of the risk mitigations, with references to specific risk management file artifacts and requirements, See ISO 14971:2019 Cl. 7.1-7.2, 7.5-7.6]

[Discussion of the overall impact on the medical device system, residual risk and labeling considerations, See ISO 14971:2019 Cl. 7.3, 7.4, 8.0]

#### Collective Impact Assessment

[Describe the collective impact of implementing all modifications]

# Authorization

|  |  |
| --- | --- |
| Has this PCCP been previously authorized by the FDA?  Yes  No  If yes, list the premarket approval and the document number and version submitted. | Premarket approval: K1234567  Document and version: VAL-XXXXX version 0.1  N/A |

# Revision History

| Version | Changes |
| --- | --- |
| 1.0 | * New Document |

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