

**SUMMARY OF: P910023/S342, P030054/S273, P030035/S123, P970013/S060,
P880086/S245, AND P880006/S089**

**MODEL 3330 VERSION 19.1 SOFTWARE FOR THE MODEL 3650 MERLIN PATIENT CARE
SYSTEM PROGRAMMER**

Executive Summary

St. Jude Medical is requesting approval for the new Model 3330 version 19.1 software for use on the Model 3650 Merlin™ Patient Care System (PCS) Programmer. The Merlin 19.1 PCS Programmer software is based on the Merlin 18.1.1 PCS Programmer Software which was granted FDA approval on May 29, 2014 (P910023/S333).

Software Description and Modifications

Software changes are listed in the submission. These include feature enhancements, parameter display changes/enhancements, code robustness changes, and changes made as a result of field issues. I have reviewed these changes thoroughly and do not have any major concerns. Via telephone on September 3, 2014, I asked the sponsor several clarification questions regarding Changes #2 and #4. The sponsor responded to these questions via e-mail on September 8, 2014. These questions and the sponsor's responses can be found below:

Change #2 Description: Made changes to the software to restore the Remaining Battery Capacity (RBC) display. Modified the logic to use the (b)(4) TS/CCI) in calculating RBC and longevity estimates until a valid postimplant battery measurement is recorded. Also added a warning message to the user, if the voltage is below a pre-determined threshold prior to implant.

FDA Questions: Has this logic been validated in previous submissions to calculate RBC and longevity? Is there a change to the battery longevity calculation itself or change to the display on the programmer?

SJM Response: The RBC (Remaining Battery Capacity) display and both the RBC and the longevity estimate calculations are changing for low voltage device families. We are re-introducing the RBC display on the screen. The calculation of RBC is now based on the (b)(4) TS/CCI until a valid post-implant battery measurement is recorded. Then the calculation is based on both the (b)(4) TS/CCI , as done previously. The change is to remove the effect of differences in battery voltage (b)(4) TS/CCI that may produce misleading results. The RBC is an input to the longevity estimate calculation, which will now have improved accuracy prior to a valid post-implant battery measurement. After a valid post-implant battery measurement is recorded, both the remaining battery capacity display and the longevity estimate are calculated in the previous manner.

Reviewer Comments: The changes to the RBC calculation are acceptable and do not introduce any new safety or effectiveness concerns. The sponsor is accounting for the temperature the device will be stored in before implantation. The sponsor was asked a follow-up question to determine if the established battery longevity estimations are changing as a result of this revised calculation. The sponsor stated that the longevity

estimates are not changing and the labeling has not been revised. This information is acceptable.

Change #4 Description: Added a flag in the device to indicate the participation of the patient in a study and the ability of the Merlin PCS to read this flag. Upon detection of such device, the Merlin PCS displays a notification dialog on the screen with instructions to the user.

FDA Questions: Was this a firmware change? What is the mechanism used to assign the flag and display on the programmer?

SJM Response: This change was made in the programmer software only. There are no changes in the firmware as part of this program. For this particular change, the Merlin PCS programmer software simply writes to a pre-allocated memory of the device that is controlled by the programmer.

Reviewer Comments: This information is acceptable. The firmware is not being modified and the software change does not introduce harm to the patient; it is a mechanism to keep track of patients in studies. I have no further concerns.

Level of Concern

The Level of Concern is Major for the Merlin PCS Programmer Software: A failure or latent flaw could directly result in death or serious injury to the patient. The software provides diagnostic information that directly drives decisions regarding treatment or therapy. ***This information is acceptable.***

Software Requirements Specification (SRS)

The Software Requirements Specification (SRS) is provided in the original submission (PMA, 180-day PMA-S) for the new software application/platform. The new and modified software requirements are defined in the Delta SRS: "Merlin 19.1 PCS Delta Software Requirements Specification (SRS)".

Reviewer Comments: Although the sponsor did not provide the full Software Requirements Specification in the submission, the Delta SRS provides an adequate description of the new and modified software requirements and their functions. This information is acceptable.

Device Hazard Analysis

The Risk Management Report for Merlin 19.1 PCS Programmer Software describes the methods used to assess risk for the Merlin Programmer Software. St. Jude Medical System Risk Management is a systematic process used to identify hazards, estimate risks, evaluate and control risks, and verify the effectiveness of risk control measures/mitigations. Through the Risk/Hazard Analysis process, potential safety risks to the patient, user and environment are identified, and these potential risks are evaluated. Controls to mitigate the potential risks are identified and implemented to achieve an acceptable residual risk level.

Any new hazards or causes associated with the new software features/modifications were analyzed and mitigated. All the risks are As Low As Reasonably Practicable (ALARP) or Broadly Acceptable, and the overall risk remains acceptable.

Reviewer Comments: All risks/hazards associated with the software modifications seem to be properly mitigated according to the risk assessment by the sponsor. I have no further concerns.

Architecture Design Chart

There was no overall change to the software architecture due to the modifications included in the Merlin 19.1 PCS Programmer Software.

Reviewer Comments: Based on the nature of the changes, I agree that the software architecture does not need to be altered. This information is acceptable.

Traceability Analysis

The sponsor has provided a traceability analysis which links the hazard analysis, requirements specification documentation, architecture design chart, design specification documentation, verification tests, and test results to the changes made the software. All changes have an associated test and all tests passed. ***This information is acceptable.***

Software Development Environment Description

The sponsor has provided the Software Development Environment Description in the submission. The overall software development environment has not changed due to the modifications made in this software version. The Merlin 19.1 PCS Programmer Software was developed using an iterative development life cycle. Some concepts of the (b)(4) TS/CCI software development methodology have been incorporated into SJM's processes. ***This information is acceptable.***

Revision Level History

The sponsor provided the following revision level history for the Merlin 19.1 PCS Programmer Software. ***This information is acceptable.***

Release Version	Programmer Release (PR)	Date	Description of Change
1	(b)(4) TS/CCI		<ul style="list-style-type: none"> • New Features and New Model Support. • Integrated major features. • Used for Integration testing.
2			<ul style="list-style-type: none"> • Software used for Verification Dry Run.
3			<ul style="list-style-type: none"> • Software release used for the start of Final Verification Testing.
4			<ul style="list-style-type: none"> • Final Programmer Release version.

Software Verification

The Software Verification Report (SVR), which can be found in the submission, summarizes the results of software verification activities conducted for Merlin PCS 19.1 Programmer Software version. The SVR contains a description of testing activities and test results as well as description of modifications made to the software as a result of any failed tests.

Both static and dynamic analysis verification activities were performed during testing. There were (b)(4) TS/CCI changes incorporated into the software during final verification testing. Appropriate regression testing was performed as a result of these changes and I have no further concerns.

There were six (6) unresolved anomalies in the Merlin 19.1 PCS Programmer Software code. I have reviewed these anomalies and do not believe they introduce significant risk to the patient. Mitigations and workarounds are in place. Via telephone on September 4, the sponsor was asked to clarify if Unresolved Anomaly #1 (Description: In two field cases, (b)(4) TS/CCI (b)(4) TS/CCI was reported by the programmer while using a normally functioning Accent device) was seen in the field or during field testing. If the anomaly was experience by users in the field, the sponsor was asked to indicate if the field issue was properly reported to FDA. The sponsor responded via e-mail on September 8, 2014 and explained that the issue was reported by users in the field. The SJM field representative submitted a trouble ticket to a database repository, which was then evaluated by SJM expert personnel for further action. This shows that there is a system in place to determine issues in the software and this is acceptable.

System Validation

The sponsor provided the System Verification and Validation Report in the submission. The legacy test design is comprised of in-clinic flows for testing basic functionality of SJM high voltage and low voltage devices. These flows evaluate the system during a simulated clinical workflow including implant, out-of-clinic, and follow-up scenarios. They also test the device setup, programming, and in-clinic tests. Additional testing was performed to ensure programmer/device safety functionality, including EVVI and commanded shock. Testing was run on a variety of devices to ensure programmer functionality. All tests passed and no anomalies were found during testing. ***This information is acceptable.***

Labeling

The Merlin PCS Programmer Help Manual was updated to include information for the modifications discussed in the submission. Redlined and clean copies of the Merlin PCS Help Manual are included in the submission. The Merlin PCS Programmer Start-Up Screen Help Manual has also been updated. Redlined and clean copies of the Merlin PCS Start-Up Screen Help Manual are also included in the submission. ***These modifications are acceptable and I have no further concerns.***

Conclusion and Recommendation

Based on the information provided by the sponsor in the submission and through e-mail correspondence, I believe that the changes made to the programmer are acceptable. All verification and validation activities were carried out adequately and the software meets all requirements and is ready for use. All unresolved anomalies are acceptable. I have no further concerns.