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SIGNATURES

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Revision History

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| **Rev.** |  | **Date** |  | **Initials** |  | **Description** |
| 0.1 |  | 29-Oct-2018 |  | KW |  | Initial Release for Review |
| 0.2 |  | 16-Apr-2019 |  | DAT |  | Replace Connected Tower Bridge with INTELLIO Link, update address of VSS |
| 0.3 |  | 01-Aug-2019 |  | KW |  | Corrected SAP # for the DFMEA and added additional documents to the Software Lifecycle Documents table |
| A |  | 26-Sep-2019 |  | DAT |  | Updated to Revision A |
| B |  | 19-Jan-2021 |  | DAT |  | Add maintenance plan for software version 3.00 |

Glossary

R&D – Research and Development

SQA – Software Quality Assurance

RA – Regulatory

Mktg – Marketing

CA – Competent Authorities

STL – Software Technical Lead

MFG – Manufacturing

QE – Quality Engineer

ECR – Engineering Change Request

ECO – Engineering Change Order; the result of approving an ECR per the Engineering Change ECR Process.

SAP – Document Control System used by the Document Control System Procedure.

References

1. 1400004 – Software Level of Concern Analysis
2. 1400003 – Software Realization Process
3. 1400020 – Design Failure Modes & Effects Analysis/Risk Analysis Procedure
4. 1400160 – Technical Review Process
5. 14000184 – Software Validation Process
6. 14000095 – Engineering Change ECR Process
7. 1400019 – Document Control System Procedure

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# Overview

The DYONICS POWER II is a microprocessor-controlled system that provides for variable speed operation of the cutting tools, and displays user prompts and system diagnostic codes. The shaver control unit can also drive high-powered arthroscopic instruments (i.e., drills, wire/pin drivers, sagittal saws). This system also will allow simultaneous use of two handpieces. Primary system components consist of a main control unit, a pump system interface cable, footswitches, handpieces and international power cords.

# Software Development Plan

## Software Development Processes

All processes of software development are defined by the Software Realization Process, (SAP #1400003).

## Software Development Documentation and Deliverables

All software development documentation and deliverables including what stage of software development they are produced are defined by the Software Realization Process, (SAP #1400003). A detailed list of software development documentation and deliverables is as follows:

### DYONICS POWER II Software Lifecycle Documents

| Title | Purpose | Intended Audience | Development, Modification,  Review and Approval | Reference | Status for Version 3.00 |
| --- | --- | --- | --- | --- | --- |
| DYONICS POWER II UNDI | Describe the User Needs and Design Inputs that drive the design of the DYONICS POWER II Control System. | Project team, R&D, QA, RA, Mktg, MFG, Packaging and CA | User Needs, Design Inputs & Design Outputs (SAP #14000031) | SAP #15008058 | Unchanged Rev C |
| DYONICS POWER II System Specification | Describe the top level Hardware and Software components of the DYONICS POWER II Control System. | Project team, R&D, MFG and CA | Design Controls Procedure (SAP #1420006) | SAP #15000694 | Update to Rev C |
| DYONICS POWER II Software Level of Concern | Assign a Software Level of Concern given the severity of injury that a device could permit or inflict as a result of latent failures, design flaws, or using the medical device software. | Project team, R&D, SQA, RA and CA | Software Level of Concern Analysis (SAP #1400004) | SAP #15008021 | Update to Rev B |
| DYONICS POWER II Software Safety Classification | Determine Software Safety Class given the possible effects on the patient, operator, or other people resulting from a hazard to which the software system can contribute. | Project team, R&D, SQA, RA and CA | Software Realization Process (SAP #1400003) | SAP #15006474 | Update to Rev C |
| DYONICS POWER II Software Development Plan | Describe how the project will create the software including the tools, schedule, assumptions, constraints, deliverables, and other activities needed to realize the software product. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008077 | Update to Rev B |
| DYONICS POWER II Software Description | Provide an overview of the features that are controlled by software and a description of the intended operational environment. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008080 | Unchanged Rev A |
| DYONICS POWER II Software Architecture Design Chart | Depict the relationships among the major functional units in the Software Device, including relationships to hardware and to data flows. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008082 | Unchanged Rev A |
| DYONICS POWER II Software Architecture Description | Transform the software requirements into a documented architecture including SOUP components and risk control. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008083 | Update to Rev B |
| DYONICS POWER II Software Development Environment Description | Summarize the software life cycle development plan and the configuration management and maintenance activities. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008081 | Unchanged Rev A |
| DYONICS POWER II System Controller Software Requirements Specification | Document the essential requirements (e.g., functional, performance, design constraints, and attributes) of the software and its external interfaces. | Project team, R&D, Mktg, SQA and CA | Software Realization Process (SAP #1400003) | SAP #15000695 | Update to Rev D |
| DYONICS POWER II Motor Controller Software Requirements Specification | Document the essential requirements (e.g., functional, performance, design constraints, and attributes) of the software and its external interfaces. | Project team, R&D, Mktg, SQA and CA | Software Realization Process (SAP #1400003) | SAP #15000701 | Unchanged at Rev B |
| DYONICS POWER II Footswitch Software Requirements Specification | Document the essential requirements (e.g., functional, performance, design constraints, and attributes) of the software and its external interfaces. | Project team, R&D, Mktg, SQA and CA | Software Realization Process (SAP #1400003) | SAP #15000283 | Unchanged at Rev A |
| DYONICS POWER II System Controller Software Design Specification | Document the details of how the requirements for a software system will be implemented. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000696 | Update to Rev C |
| DYONICS POWER II Motor Controller Software Design Specification | Document the details of how the requirements for a software system will be implemented. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000702 | Unchanged at Rev B |
| DYONICS POWER II Footswitch Software Design Specification | Document the details of how the requirements for a software system will be implemented. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000284 | Unchanged at Rev A |
| DYONICS POWER II Software Upgrade and Repair Specification | Document the details of how the System Controller and Motor Controller software is updated and repaired. | Project team, R&D, Mktg, SQA and CA | Software Realization Process (SAP #1400003) | SAP #15000768 | Unchanged at Rev B |
| DYONICS POWER II INTELLIO Link Protocol Specification | Document the details of how the DYONICS II EIP communicates with the INTELLIO Link. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15007915 | Unchanged at Rev A |
| DYONICS POWER II Inter-Controller Communications Protocol | Document the details of how the DYONICS II EIP System Controller and Motor Controller communicate. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000721 | Unchanged at Rev A |
| DYONICS POWER II Shaver Pump Interface Protocol | Document the details of how the DYONICS II EIP communicates with Smith & Nephew Pumps. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000285 | Unchanged at Rev C |
| DYONICS POWER II RS485 Accessory Protocol | Document the details of how the DYONICS II EIP communicates with Smith & Nephew RS485 based Handpieces and Footswitches. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000286 | Unchanged at Rev B |
| Reliant RS485 Protocol Specification | Document the details of how the DYONICS II EIP communicates with Smith & Nephew Reliant RS485 based Handpiece. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008940 | Unchanged at Rev A |
| DYONICS POWER II System Controller Software Unit Tests | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000697 | Update to Rev C |
| DYONICS POWER II Motor Controller Software Unit Tests | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000703 | Unchanged at Rev B |
| DYONICS POWER II Footswitch Software Unit Tests | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000303 | Unchanged at Rev B |
| DYONICS POWER II Software Upgrade and Repair Verification | Describe and record the execution of the verification protocol which describes how all functions that implement Software Requirements, Basic Safety, Essential Performance, or Risk Control measures will be verified. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008093 signed protocol, test and results attached to the ECO of software documentation | Unchanged at Rev A |
| DYONICS POWER II INTELLIO Link Protocol Verification | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008643 signed protocol, test and results attached to the ECO of software documentation | Unchanged at Rev A |
| DYONICS POWER II Inter-Controller Communication Verification | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000722 signed protocol, test and results attached to ECO of software documentation | Unchanged at Rev B |
| DYONICS POWER II Shaver Pump Interface Verification | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000355 signed protocol, test and results attached to ECO of software documentation | Unchanged at Rev C |
| DYONICS POWER RS485 Accessory Protocol Verification | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000704 signed protocol, test and results attached to ECO of software documentation | Unchanged at Rev B |
| Reliant RS485 Protocol Verification | Describe and record the execution of a set of tests on individual software units to demonstrate functionality of the software not otherwise visible through System Testing. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15008986 | Unchanged at Rev A |
| DYONICS POWER II Software Trace Matrix | Describe traceability between the requirements of design inputs, usability and risk control measure with the requirements specification, design specifications and tests. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000699 | Unchanged at Rev B |
| DYONICS POWER II System Software Verification | Describe and record the execution of the verification protocol which describes how all functions that implement Software Requirements, Basic Safety, Essential Performance, or Risk Control measures will be verified. | Project team, R&D and CA | Software Realization Process (SAP #1400003) | SAP #15000700 signed protocol, test and results attached to ECO of software documentation | Update to Rev C |
| DYONICS POWER II System Software Validation | Describe and record the execution of the validation protocol which determines that the software specifications conform to user needs. | Project team, R&D, Mktg, RA, SQA and CA | Software Validation Process (SAP #14000184) | SAP #15000817 signed protocol, test and results attached to the software validation ECO | Update to Rev C |

### DYONICS POWER II Risk Management Documents

| Title | Purpose | Intended Audience | Development, Modification,  Review and Approval | Reference | Status for Version 3.00 |
| --- | --- | --- | --- | --- | --- |
| DYONICS POWER II DFMEA | List identified hazards, detail how these hazards are controlled and assess the overall residual risk of software. | Project team, R&D, RA, QE, MFG, Mktg and CA | Design Failure Modes & Effects Analysis/Risk Analysis Procedure (SAP #1400020) | SAP #16000043 | Update to Rev R |
| DYONICS POWER II Risk Analysis | Identify product to be analyzed and identify product characteristics affecting safety | Project team, R&D, RA, QE, MFG, Mktg and CA | Design Failure Modes & Effects Analysis/Risk Analysis Procedure (SAP #1400020) | SAP #16500014 | Unchanged at Rev H |

### DYONICS POWER II Design Reviews Actions and Resolutions

| Title | Purpose | Intended Audience | Development, Modification,  Review and Approval | Reference |
| --- | --- | --- | --- | --- |
| DYONICS POWER II Design Reviews Actions and Resolutions | Describe and record the execution of a technical design reviews for software implementation of requirements. | Project team, Design Review Team and CA | Software Realization Process (SAP #1400003) | SAP #1440425  signed and attached to the ECO of software documentation |

### DYONICS POWER II Software Revision Level History

| Title | Purpose | Intended Audience | Development, Modification,  Review and Approval | Reference |
| --- | --- | --- | --- | --- |
| DYONICS POWER II Software Revision Level History | Provide detail of use of software revision control during the development. | Project team, R&D, RA and CA | STL  R&D | Signed and attached to the ECO of software documentation |

### DYONICS POWER II Software Binary and Source

| Title | Purpose | Intended Audience | Development, Modification,  Review and Approval | Reference |
| --- | --- | --- | --- | --- |
| DYONICS POWER II System Software Binary and Source | Provide the verified and validated software that is to be released in source and binary form. | R&D and CA | STL  R&D | SAP #73000196 |

Documents updated as part of this maintenance release may remain on the versions of the templates that were previously in use, per 1400003 rev N, section 5.4.2.

## Software Traceability

The traceability between Design Inputs, Software Requirements, Software Descriptions, Software Units Tests and Software Verification including risk control measures are defined in the DYONICS POWER II Software Trace Matrix document, (SAP #15000699).

## Software Configuration and Change Management

The DYONICS POWER II software development items that are placed under configuration management, when and how they are controlled and who manages the control is as follows:

### DYONICS POWER II Software Development Documentation and Deliverables Configuration Items

| Software Development Documentation and Deliverables Configuration Items | Control |
| --- | --- |
| **2.2.1 DYONICS POWER II Software Lifecycle Documents** | These items are initially created or modified according to the Software Realization Process, (SAP #1400003). They are placed under management using Microsoft Visual Source Safe 2005 in the “Controlsgroup” database at “[\\Usashsmnas01\VSS\Controlsgroup](file:///\\Usashsmnas01\VSS\Controlsgroup)” under “$/R\_D/DII-EIP”. Changes during this phase are tracked via numeric revisions in the documents. As part of the ECO release of the software the documents are assigned a letter revision for new documents or given and controlled using SAP. Any changes to the documents after this point are tracked by the revision letter using SAP. 14000095 |
| **2.2.2 DYONICS POWER II Risk Management Documents** | These items are initially created and updated according to the Design Failure Modes & Effects Analysis/Risk Analysis Procedure (SAP #1400020) and are released via an ECO. |
| **2.2.3 DYONICS POWER II Design Review Actions and Resolutions** | The Design Reviews, (including Code Reviews), are performed according to the Technical Review Process (SAP #1400160) and the resulting completed Design Form (SAP #1440425) are signed and included in the ECO release of software documentation. |
| **2.2.4 DYONICS POWER II Software Revision Level History** | A report is generated from Microsoft Visual Source Safe 2005 of all the revision activity that occurred during the development of the DYONICS POWER II. This report is signed and included in the ECO release of software documentation. |
| **2.2.5 DYONICS POWER II Software Binary and Source** | The source code, (including build configuration files), are initially created according to the Software Realization Process, (SAP #1400003). The source code is placed under management using Microsoft Visual Source Safe 2005 in the “Controlsgroup” database at “[\\Usashsmnas01\VSS\Controlsgroup](file:///\\Usashsmnas01\VSS\Controlsgroup)” under “$/R\_D/DII-EIP”. At the stage of Code Freeze all the source code is checked in and labeled under Visual Source Safe as a release candidate and no changes are allowed until after Verification Testing. As part of the first ECO release of the software the source code and output files are put in a zip file and controlled using SAP. |

### DYONICS POWER II Software Development Tools Configuration Items

| Software Development Tools Configuration Items | Control |
| --- | --- |
| **Windows CE 5.0 with Platform Builder,**  **Windows CE 5.0 2009 Rollup,**  **eVC 4 SP4,**  **AT91SAM9263EK\_CE5\_v100,**  **Patch\_AT91SAM9263EK\_SRC\_v100\_24072007,**  **CodeWarrior 8.2.3 56800E,**  **J-Link ARM 4.02,**  **GNU make-3.81,**  **yagarto-bu-2.17\_gcc-4.1.1-c-c++\_nl-1.14.0\_gi-6.5.5,**  **Visual SourceSafe 2005,**  **Visual Studio Pro 2005** | The installation media for the software development tools are placed into DHF 27500442. |

## Software Issue Resolution

Issues will be tracked per the Software Issue Classification Procedure (SAP#1400158) using an Excel Spreadsheet and the final result will be attached to the V&V reports per the New Development procedure in the Software Realization Process, (SAP #1400003).

## System Requirements

The DYONICS POWER II system software requirements are covered the DYONICS POWER II System Controller Software Requirements Specification (SAP #15000695), the DYONICS POWER II Motor Controller Software Requirements Specification (SAP #15000701), the DYONICS POWER II Footswitch Software Requirements Specification (SAP #15000283), the DYONICS POWER II Software Upgrade and Repair Specification (SAP #15000768), the Connected Tower Bridge DYONICS POWER II Specification (SAP #15007915), the DYONICS POWER II Inter-Controller Communications Protocol (SAP #15000721), the DYONICS POWER II Shaver Pump Interface Protocol (SAP #15000285), the DYONICS POWER II RS485 Accessory Protocol (SAP #15000286) and the Reliant RS485 Protocol Specification (SAP #15008940).

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## Software Validation

The DYONICS POWER II Software Validation procedures are defined by the Software Validation Process, (SAP #14000184).

## Standards, Methods and Tools (for Class C Software)

The DYONICS POWER II was declared Class B per the DYONICS POWER II Software Safety Classification Review held on 10-Oct-2018, (SAP # 15006474). Therefore this does not apply.

## Software Integration and Verification

The Software Integration is defined in section 2.4.

The Software Verification is included in DYONICS POWER II System Software Verification document (SAP #15000700).

## Software Risk Management Activities

The Software Risk Management will be encompassed by the Risk Analysis document, (SAP #16500014) and Software DFMEA document, (SAP #16000043).

## Software Development Environment

The Software Development Environment is specified in the Software Description document, (SAP #15008080).

## Software Source Control

The Software Source Control will be managed on Microsoft Visual SourceSafe 2005 in the “Controlsgroup” database at “[\\Usashsmnas01\VSS\Controlsgroup](file:///\\Usashsmnas01\VSS\Controlsgroup)” under “$/R\_D/DII-EIP”.

## Software Maintenance Release

The software is be updated to support the changes requested for the DYONICS POWER II BF project. The changes have limited impact to the software. Affected documents will be updated to reflect changes to the design changes and risk management. Unaffected documents will remain at their current revisions. Regression testing will be conducted as indicated by the Software Trace Matrix. The overall design functionality of the software will be confirmed through execution of the DYONICS POWER II System Software Verification. Compliance to the User Needs and Design inputs will be validated through execution of the DYONICS POWER II System Software Validation.