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Revision History

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| **Rev.** |  | **Date** |  | **Initials** |  | **Description** |
| 0.1 |  | 05-Mar-2009 |  | DAT |  | Initial draft derived from 15000279 Rev 1.4 |
| 0.2 |  | 27-Mar-2009 |  | KW |  | Removed power button interface |
| 0.3 |  | 03-Apr-2009 |  | KW |  | Added SQA signature per EOP 1400003 Rev F. |
| 0.4 |  | 09-Jun-2009 |  | DAT |  | Updated based upon Design Review |
| 0.5 |  | 30-Jul-2009 |  | DAT |  | Added EIP to Document Title |
| A |  | 16-Oct-2009 |  | DAT |  | Initial Release |
| B |  | 05-Feb-2019 |  | KW |  | Updated to OP 1400003 Rev K Template  Replaced CONDOR with INTELLIO Link  Removed unsupported products  Expanded INTELLIO Link and Pump Interface |
| C |  | 03-Jul-2019 |  | KW |  | Add System and Handpiece Identification Requirements  Add requirement for reporting an estimate of the number of procedures a system has been used in. |
| D |  | 01-Jan-2021 |  | DAT |  | Reduce supported Footswitches to DYONICS POWER II Footswitch 72201092 and Pedal Style 7205396  Reduce supported Power Instrument handpiece support to Pistol Grip Drill 7205785 and Inline Sagittal Saw 7205786  Remove support of 7205971 DYONICS POWER UltraLight MDU |

Glossary

|  |  |
| --- | --- |
| ***Set Speed*** | *The target speed for handpiece. Set Speed will be in units of RPM, RATE or % of Full Power depending on the operating mode of the handpiece.* |
| ***Set Speed Adjustment*** | *Changes to the Set Speed via the GUI interface.* |
| ***Set Speed Adjustment Button*** | *GUI provided up and down arrow buttons provided for Set Speed Adjustment.* |
| ***OK Button*** | *GUI provided button to exit a pop-up window.* |
| ***Operational Screen and Conditions*** | *GUI provided primary screen for displaying handpiece operating status and adjusting operating parameters during a surgical procedure.* |
| ***Settings Screens*** | *GUI provided secondary screens for setting and displaying all non-operating parameters.* |

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# Overview

The System Controller shall be a primary element in an arthroscopic powered resection design that is responsible for controlling two low voltage DC motors. The System Controller shall communicate control and parametric data bi-directionally with a Motor Controller. Using a set of System Interfaces a Controlling Application shall provide a user with graphical status and touch screen control over the motor operation. It shall also optionally provide status to a DYONICS 25 Fluid Management System and status signals to and control signals from an INTELLIO Link.

# Requirements

The requirements for the System Controller are divided into two major sections, the System Interfaces and the Controlling Application.

## System Interfaces

The System Controller shall provide System Interfaces used by the Controlling Application for bootstrapping, communication, I/O and non-volatile storage.

### Boot Interface

1. The System Controller shall boot a Windows CE based application environment.
2. The System Controller shall provide a Splash Screen during the boot process.

### Software Upgrade Interface

1. The System Controller shall provide a means to upgrade the software via an external USB port.
2. Any interruption of the upgrade process shall not allow the software to cease functioning.

### Serial Port Interfaces

1. The System Controller shall support a serial port interface for INTELLIO Link communication.
2. The System Controller shall support a serial port interface for Pump/Shaver communication.
3. The System Controller shall support a serial port interface for future communication.

### Display Interface

The System Controller shall support an 800 x 480 pixel color graphics display for the Controlling Application.

### Touch Screen Interface

The System Controller shall support touch panel positional data for the Controlling Application button control.

### Motor Controller Interface

The System Controller shall communicate variable length control and parametric data packets bi-directionally to a Motor Controller via a parallel communication interface.

### Non-volatile Storage Interface

1. The System Controller shall provide battery backed up non-volatile RAM storage for the Setting Screens.
2. The System Controller shall provide non-volatile FLASH storage for the Boot Interface.
3. The System Controller shall provide non-volatile FLASH storage for the Software Upgrade Interface.
4. The System Controller shall provide non-volatile FLASH storage for Blade Recall Mode.
5. The System Controller shall provide non-volatile FLASH storage for Serial Number of the DYONICS POWER II.
6. The System Controller shall provide non-volatile FLASH storage for recording the number of times the DYONICS POWER II is powered on and a handpiece activated.

## Graphical User Interface

The System Controller shall provide a Graphical User Interface (GUI) that will guide the user through the startup and operating modes via an interactive series of touch/display screens.

### Icons

1. GUI shall display a Pump Icon when a DYONICS 25 Fluid Management System is connected through the Pump Interface or a when there is a pump present through the INTELLIO Link. The Pump Icon shall be blue and spin when the pump is running and gray when the pump is not running.
2. GUI shall display an INTELLIO Link icon when an INTELLIO Link connection is detected.
3. GUI shall display a Footswitch icon when a Footswitch is connected.
4. GUI shall display an MDU icon when an MDU is connected.
5. GUI shall display a Saw icon when a Saw is connected.
6. GUI shall display a Drill icon when a Drill is connected.

### INTELLIO Link Interface

1. Application shall provide identification of its device type to the INTELLIO Link Interface.
2. Application shall provide its readiness status on the INTELLIO Link Interface.
3. Application shall publish changes of handpiece set speed, set speed units, mode and blade family settings to the INTELLIO Link Interface.
4. Application shall publish changes to availability of set speed adjustment to the INTELLIO Link Interface.
5. Application shall publish changes of the handpiece run state to the INTELLIO Link Interface.
6. Application shall publish errors and warnings to the INTELLIO Link Interface.
7. Application shall publish and accept requests for changes of its Handpiece Override, Blade Default/Blade Recall, Footswitch Port and Pump Port settings to the INTELLIO Link Interface.
8. Application shall provide means to save the Non-volatile Storage to the INTELLIO Link Interface for later retrieval.
9. Application shall provide a means to restore the Non-volatile Storage from the INTELLIO Link Interface.
10. Application shall publish a Lavage Toggle event from the DYONICS POWER II Footswitch to the INTELLIO Link Interface.
11. Application shall accept set speed adjustment, oscillate mode toggle and pop-up OK button press commands from the INTELLIO Link Interface.
12. Application shall accept an exit Settings Screen command from the INTELLIO Link Interface.
13. Application shall update the GUI with changes requested from the INTELLIO Link Interface.
14. Application shall receive pump connect and running state through the INTELLIO Link Interface when a pump is available through the INTELLIO Link.
15. Application shall update the GUI with pump connect and running state when there is no Pump Interface connection and a pump is available through the INTELLIO Link .
16. Application shall provide the Serial Number of the DYONICS POWER II to the INTELLIO Link Interface.
17. Application shall provide the Serial Number of handpieces that have the capability to report them to the INTELLIO Link Interface.

### Pump Interface

1. Application shall support communication with a DYONICS 25 Fluid Management System.
2. Application shall receive the pump connect and running state from the Pump Interface.
3. Application shall publish the type of shaver, handpiece mode and handpiece blade family on the Pump Interface.
4. Application shall publish a Lavage Toggle event from the DYONICS POWER II Footswitch to the Pump Interface.

### Operational Screens and Conditions

1. GUI shall be divided into two ports. Port A shall be on the left side of the display and Port B shall be on the right hand side of the screen. If a handpiece is connected to the Port A connector the GUI shall display the required information on the left hand side of the screen. If a handpiece is connected to the Port B connector the GUI shall display the required information on the right hand side of the screen.
2. Application shall provide the ability to display and control two handpieces simultaneously.
3. GUI shall provide a visual representation for a port that does not have a handpiece connected.

#### MDU

1. The GUI shall display the current mode of operation via large directional indicators to represent Forward, Reverse, Oscillate, or Window Lock.
2. GUI shall display in large font, the current RPM selection for Forward, Reverse and Oscillate Mode 1 and the current RATE selection for Oscillate Mode 2.
3. GUI shall display in small font, maximum RPM for Forward and Reverse modes of operation and unit of measure for Oscillate 1 and Oscillate 2 modes of operation. Unit of measure for Oscillate Mode 1 shall be RPM and unit of measure for Oscillate Mode 2 shall be RATE.
4. GUI shall indicate when the MDU is running.
5. GUI shall provide the ability to adjust RPM or RATE for oscillate modes by set speed adjustment.
6. GUI shall provide the ability to adjust RPM for forward and reverse modes by set speed adjustment.
7. GUI shall provide the ability to auto scroll the RPM or RATE by extended activation of a set speed adjustment button.
8. Application shall detect and handle a blade change.
9. Application shall provide full support for the following MDUs:

|  |  |
| --- | --- |
| **MDU** | **Ref** |
| DYONICS Mini-Motor Drive | 7205357 |
| DYONICS PowerMax Elite | 72200616 |
| DYONICS PowerMax Elite | 72200617 |
| DYONICS PowerMax Elite | 72200872 |
| DYONICS PowerMax Elite | 72202546 |
| DYONICS PowerMini | 72201500 |
| DYONICS PowerMini | 72201503 |

1. GUI shall provide the ability to toggle between Oscillate Mode 1 and 2 for handpieces that support it.
2. Application shall provide full support for MDUs with hand controls.
3. Application shall provide full support for MDUs without hand controls.
4. Application shall provide an expandable interface that permits the support of additional MDUs and blade families.
5. Application shall provide a mechanism to set the Window Lock position via the GUI when an MDU is connected.

#### Powered Instrument

1. GUI shall display the current mode of operation via large directional indicators to represent forward or reverse for a drill and oscillate for a saw.
2. GUI shall indicate when the Powered Instrument is running.
3. GUI shall display in large font, the current % of Full Power.
4. GUI shall provide the ability to adjust the % of Full Power by set speed adjustment.
5. GUI shall provide the ability to auto scroll the % of Full Power by extended activation of a set speed adjustment button.
6. Application shall provide full support for the following Powered Instruments:

|  |  |
| --- | --- |
| **Powered Instrument** | **REF** |
| Pistol Grip Drill | 7205785 |
| Inline Sagittal Saw | 7205786 |

#### Oscillate Modes

##### Mode 1

GUI shall indicate Oscillate Mode 1 selection by displaying the text “Mode 1” when an MDU is connected and running in oscillate mode.

##### Mode 2

GUI shall indicate Oscillate Mode 2 selection by displaying the text “Mode 2” when an MDU is connected and running in oscillate mode.

#### Footswitch

1. Application shall provide a mechanism for a connected footswitch to run and control the direction of a handpiece.
2. Application shall provide the ability to start and stop the lavage process on a connected DYONICS 25 Fluid Management System.
3. Application shall provide full support for the following Footswitches:

|  |  |
| --- | --- |
| **Footswitch** | **REF** |
| Pedal Style | 7205396 |
| DYONICS POWER II Footswitch | 72201092 |

1. Application shall provide a mechanism to support set speed adjustment from the footswitch.
2. Application shall provide a mechanism to set the Window Lock position from the footswitch.

#### Warnings / Faults

1. GUI shall display a single line message when a warning is detected.
2. A single line message shall describe the warning.
3. A single line message shall be black text with a yellow background.
4. GUI shall display a full screen detailed message if the yellow single line message is touched describing the warning in detail.
5. A full screen detailed message shall provide a button to return to the previous screen.
6. Application shall reduce functionality when warranted to maintain safe operation in the event of certain warning conditions.
7. GUI shall display a system warning popup message that requires a user response in the event that a system warning occurs.
8. GUI shall display a fatal error screen and shut down the motors in the event that a catastrophic failure occurs.

### Settings Screens

Application shall provide a mechanism for the user to configure and save supported control parameters into battery backed up non-volatile RAM and save last used blade speeds settings into non-volatile FLASH.

#### Blade Reset

Application shall provide a mechanism to return Set Speeds and % of Full Power to default values on a per port basis.

#### Blade Recall / Blade Default Mode

1. Application shall provide a means to select Blade Recall or Blade Default mode of operation.
2. Application shall save into non-volatile FLASH last settings of oscillate, forward and reverse, if Blade Recall mode of operation is selected.
3. Application shall save into non-volatile FLASH last settings of oscillate, forward and reverse, per blade family, if an MDU that supports blade detection is connected.
4. Application shall initialize from non-volatile FLASH oscillate, forward and reverse settings if Blade Recall mode of operation is selected and a handpiece is connected at power up.
5. Application shall initialize default oscillate, forward and reverse settings if Blade Default mode of operation is selected and a handpiece is connected at power up.
6. Application shall initialize from non-volatile FLASH oscillate, forward and reverse settings if Blade Recall mode of operation is selected and a handpiece is connected after power up.
7. Application shall not replace current settings for oscillate, forward and reverse if Blade Default mode of operation is selected and a handpiece is connected after power up.

#### Oscillate Modes

1. Application shall provide optimized oscillate mode by default.
2. Application shall provide ability to select a custom oscillate mode instead of default mode if it’s determined that the MDU is able to support a custom oscillate mode.

##### Mode 1

Application shall provide ability to adjust time.

##### Mode 2

Application shall provide ability to adjust number of rotations.

#### Footswitch

1. Application shall provide the ability to configure a variable speed footswitch as an On/Off footswitch.
2. Application shall provide a mechanism to use the footswitch in either port, A or B.
3. Application shall provide the ability to set a hand-controlled handpiece to use either the hand controls or the footswitch controls depending on which one is triggered first.
4. Application shall provide the ability to swap the Forward and Reverse pedals on the DYONICS POWER II Footswitch.
5. Application shall provide a mechanism for footswitch controls to override hand controls of an MDU.

#### Pump Interface

Application shall provide the ability to communicate with the DYONICS 25 Fluid Management System using either Port A or Port B.

#### System Information

1. GUI shall display Product name, Model Number, Copyright and Software revision levels.
2. GUI shall provide a mechanism to perform a System Reset that will reset all saved settings.
3. GUI shall display the Serial Number of the DYONICS POWER II.
4. GUI shall display the Serial Number of handpieces that have the capability to report them.

#### Language

1. Application shall provide language support for English, German, Italian, Spanish, French, Danish, Dutch, Norwegian, Portuguese, and Swedish.

### Board and System Tests

1. The Application shall provide Board Tests which are means to verify proper board operation.
2. The Board Tests shall indicate a Pass/Fail status of tests performed.
3. The Board Tests operation shall be triggered by a special USB key present during the power up of the system.
4. The Application shall provide System Tests which are means to verify proper hardware configuration and operation.
5. The System Tests shall indicate a Pass/Fail status of tests performed.
6. The System Tests operation shall be triggered by a special USB key present during the power up of the system.
7. The Board and System Tests shall provide a mechanism to reset the Settings and Blades to Factory default.
8. The Board and System Tests shall provide a mechanism to repeat a failed test.
9. The Board and System Tests shall provide a mechanism to enter and retain the Serial Number of the DYONNICS POWER II in non-volatile FLASH storage.
10. The Board and System Tests shall provide a mechanism to report the number of times the DYONICS POWER II is powered on and a handpiece activated.