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Revision History

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Rev.** |  | **Date** |  | **Initials** |  | **Description** |
| 0.1 |  | 090304 |  | DAT |  | Initial draft based upon 15000291 rev 0.3 |
| 0.2 |  | 090327 |  | KW |  | Removed unused ports |
| 0.3 |  | 090403 |  | KW |  | Eliminated vendor specific language for OEM Footswitch and updated signature lists |
| 0.4 |  | 090623 |  | DAT |  | Updated based upon design review |
| A |  | 091016 |  | DAT |  | Initial Release |
| A.1 |  | 29-Apr-2019 |  | DAT |  | Update for INTELLIO Link support, Removed future software CAN A and CAN B support, Removed CONDOR and Intelijet Support Update environmental and ship testing requirements |
| B |  | 24-Sep-2019 |  | DAT |  | Update to Revision B, Formatting updates |
| C |  | 07-Jan-2021 |  | DAT |  | Remove requirement for CAN A and CAN B implemented in11800157  Replace Power MDU and PowerMax MDU with PowerMax Elite MDU |

Glossary

MDU – Motor Drive Unit

Handpiece – MDU, Saw or Drill

References

1. 15000695 – DYONICS II EIP System Controller Software Requirements Specification
2. 15000696 – DYONICS II EIP System Controller Software Design Specification
3. 15000701 – DYONICS II EIP Motor Controller Software Requirements Specification
4. 15000702 – DYONICS II EIP Motor Controller Software Design Specification
5. 15000283 – DYONICS II Footswitch Software Requirements Specification
6. 15000284 – DYONICS II Footswitch Software Design Specification

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Dyonics II EIP System Specification

# Overview

The DYONICS II EIP 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.

## Indications for Use

The DYONICS II EIP controller is indicated for use during arthroscopic joint surgery to provide electro-mechanical resection:

* Mechanical shaving and burring-to remove soft tissue and bone as required during abrasion arthroplasty, synovectomy, and intra-articular cutting and shaving. Suction may be used via the shaver hand-piece to provide a clear surgical view by flushing away debris and blood from the joint space
* Powered instrument sawing and drilling-a corded power instrument can be driven by the controller to provide bone cutting and drilling

The System is indicated for knee, shoulder, hip, elbow, hand/wrist, foot/ankle and ENT surgery. Use of this device is contraindicated whenever arthroscopy is contraindicated and for joints other than knee, shoulder, hip, elbow, hand/wrist, foot/ankle and ENT surgery.

## System Architecture

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | Power On/Off  Switch |  |  |  |
|  |
|  |  |  |  |  |  |  |  |  | LCD |
|  |
|  |  |  |  |  |  | User Interface |  |  |  |
|  |  |
|  |  |  |  |  |  |  |  |  | Touch Panel |
|  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  | Control Unit |  |  |  |  |  | INTELLIO Link  Interface |
|  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Wired Footswitch Interface |  |  | Pump Interface |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Handpiece A  Interface |  |  | Wireless Footswitch Interface |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Handpiece B  Interface |  |  | USB 1 |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Rear Panel  Interfaces |  |  | USB 2 |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Software |  |  |  |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
| DYONICS II EIP  Power Shaver |  |  |  |  |  | Electronics |  |  |  |
|  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Cabinet |  |  |  |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  | Wired Footswitches |  |  |  |  |  |  |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  | \* Wireless Footswitch |  |  |  |  |  | PowerMax Elite MDU |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Motor Drive Units |  |  | Mini-Motor MDU |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  | Handpieces |  |  |  |  |  | PowerMini MDU |
|  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  | Powered Instruments |  |  | Drills |
|  |  |
|  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  | Oscillating Saws |
|  |
|  |  |  | **\* Not implemented for this version** | | | |  |  |  |

# Dyonics II EIP System Specification

## Front Panel Interfaces

### Power Switch

1. A push-button switch will be located on the front panel to control the secondary power of the control unit.
2. The power switch will be illuminated when control unit is on.

### Display

1. The control unit front panel will incorporate a LCD color display.
2. The display will be capable of being read in a lighted or darkened operating room.
3. The display will be capable of being read from a distance of 10 feet. Minimum viewing angles will be 50 degrees Top, 30 degrees Bottom, 50 degrees Right and 50 degrees Left.
4. The display diagonal dimension will be 7 inches nominal.

### Touch Panel

1. The touch screen is overlaid on the LCD display panel.
2. The touch screen must respond consistently to gloved and ungloved fingers.
3. The touch panel must be environmentally robust and may be wiped down with any liquid disinfecting solution; non-flammable solution should be used whenever possible.

### Wired Footswitch Interface

1. An electrical connector will be located on the control unit front panel to connect the corded footswitch to the control unit electronics.
2. The connector will be a sealed 12-pin, rear mounted (from the inside), panel-mount receptacle.
3. The receptacle must be clearly identified, remain tightly seated on the front panel and meet a minimum of 1000 connect/disconnect cycles.
4. The receptacle body and decorative panel nut materials, finish and color will be black.
5. There will be a ring surrounding the connector that will be the color black.

### Handpiece A Interface

1. An electrical connector will be located on the control unit front panel to connect the cable of the handpiece to the control unit electronics.
2. The connector will be a sealed 19-pin, rear mounted, panel-mount receptacle.
3. The receptacle must be clearly identified, remain tightly seated on the front panel and meet a minimum of 1000 connect/disconnect cycles.
4. The receptacle body and decorative panel nut materials, finish and color will be silver.
5. There will be a ring surrounding the connector that will be the color blue.

### Handpiece B Interface

1. An electrical connector will be located on the control unit front panel to connect the cable of the handpiece to the control unit electronics.
2. The connector will be a sealed 19-pin, rear mounted, panel-mount receptacle.
3. The receptacle must be clearly identified, remain tightly seated on the front panel and meet a minimum of 1000 connect/disconnect cycles.
4. The receptacle body and decorative panel nut materials, finish and color will be silver.
5. There will be a ring surrounding the connector that will be the color yellow.

## Rear Panel Interfaces

### Power Connector

1. The input power connector module will provide for connection of a detachable power cord.
2. The connector module and associated markings will be compliant with all applicable international distribution regulations.

### USB 1

Provide a USB Host connector to enable field installation of software upgrades.

### USB 2

Provide a USB Host connector to enable field installation of software upgrades.

### INTELLIO Link Interface

Provide a DB9 style female-contact connector for interface with the INTELLIO Link.

### Pump Interface

Provide a DB9 style male-contact RS-232 interface connector for use with the Smith & Nephew Dyonics 25 Fluid Management System.

### Wireless Footswitch Interface

Provide a 5 pin connector to bring out 5 V power, ground and RS-232 based signals for communications with the optional wireless footswitch module.

### CAN Bus Interface

Support for CAN BUS Interface has been removed in 11800157, as there are no accessories for this interface.

### Equipotential ground compensator

The ground compensator terminal will enable common connection of all rack-mounted equipment grounds.

### Power Supply Cooling Fan Outlet

An outlet will be provided to allow the power supply cooling fans to operate.

### Labeling

Display all necessary regulatory, product identification, and connector labeling.

## Software

The software for the Dyonics II EIP system is to be broken up into three units:

* The System Controller
* The Motor Controller
* The Wired Footswitch

The System Controller and Motor Controller software together will control all the Front Panel and all non-Power Rear Panel Interfaces. The Wired Footswitch software will receive commands from the Wired Footswitch Interface and communicate Wired Footswitch status back to the System Controller and Motor Controller. The DYONICS POWER II will support field upgrade of the System Controller and Motor Controller software via a USB key install in the back of the device.

### System Controller Software

The System Controller software will:

* Display data through the Display Interface
* Receive input from the Touch Panel Interface
* Read data from the USB 1 and USB2 Interfaces
* Communicate with INTELLIO over the INTELLIO Link Interface
* Communicate with a Dyonics 25 over the Pump Interface

The System Controller software will be written in C/C++ and assembly programming languages, compiled to binary form using Microsoft Embedded Visual C++ 4.0 and Platform Builder for Microsoft Windows CE 5.0, and run on a ATMEL AT91SAM9263 ARM Processor under the Microsoft Windows CE © 5.0 operating system.

#### System Controller Software Requirements

The System Controller Software Requirements are specified in document 15000695.

#### System Controller Software Design

The System Controller Software Design is specified in document 15000696.

### Motor Controller Software

The Motor Controller software will:

* Control a Handpiece through the Handpiece A and Handpiece B Interface.
* Interface with a wired footswitch through the Wired Footswitch Interface.

The Motor Controller software will be written in C/C++ and assembly programming languages, compiled to binary form using Freescale Code Warrior for DSC5800E and run as a single application (no operating system) on a Freescale 56F8357 microcontroller.

#### Motor Controller Software Requirements

The Motor Controller Software Requirements are specified in document 15000701.

#### Motor Controller Software Design

The Motor Controller Software Design is specified in document 15000702.

### Wired Footswitch Software

The Wired Footswitch is an accessory to the Dyonics II Control Unit. It was created by an OEM vendor for use with the Dyonics II Control Unit following design requirements from Smith & Nephew.

#### Wired Footswitch Software Requirements

The Wired Footswitch Software Requirements are specified in document 15000283.

#### Wired Footswitch Software Design

The Wired Footswitch Software Design is specified in document 15000284.

## Hardware

### Power Cycle

The user must wait at least 5 seconds after powering down the control unit before pressing the power switch to power back on the control unit.

### Power Supply

The system will provide enough power to drive two Handpieces simultaneously.

### MDU Control

A power supply and printed circuit board within the control unit will control the speed and direction of the MDU to provide mechanical shaving and burring.

### Powered Instrument Control

A power supply and printed circuit boards within the control unit will control the speed, (and drill direction if switch is present on the drill), for utilization of powered instruments (saws and drills).

### Wired Footswitch (MDU Control)

The control unit will support use of a wired footswitch to control blade action. Typical footswitches control forward, reverse, oscillate and window lock modes of operation. There are three types of footswitches, variable (analog), digital and RS485.

#### Variable Footswitches

Variable footswitches are comprised of a combination of contact switches and analog footpads. For the Forward, Reverse or Oscillate pads maximum pressure establishes 100% of set speed with each new press. Decreasing pressure on the pad allows deceleration of the MDU until the MDU stops.

#### Digital Footswitches

Digital footswitches are comprised of only contact switches.

#### RS485 Footswitches

RS485 footswitches communicate switch and pedal action digitally through an RS-485 bus to the control unit. They also support the lavage mode switch.

### Wireless Footswitch (MDU Control)

The control unit will support use of a wireless footswitch to control blade action. The wireless footswitch controls forward, reverse, oscillate, window lock and lavage modes of operation.

## Accessories

### Power Cables

Replaceable power cables compatible with US, UK, and European electrical standards will be provided.

### Dyonics 25 Interface Cable

Shielded 10 foot Null Modem Cable terminated with two retainer screw type DB9 female connectors.

## Electrical

### Voltage Range

The system must meet all performance requirements when supplied with 50/60 Hz voltage in the range of 100—120 vac and 200—240 vac.

### Safety

The system is in accordance with IEC 60601-1 and IEC 60601-1-1.

### EMC Compliance

The system is in accordance with IEC 60601-1-2.

## Mechanical

### Size

1. The control unit will be approximately 5.5 in. high x 12 in. wide x 14 in. deep and will be capable of cart mounting.
2. The control unit will be capable of mounting on a movable boom shelf with dimensions no less than 12 in. width and 14 in. depth.
3. The control unit will be capable of mounting on the S&N 72200381 and 72200747 carts.

### Weight

The control unit weight will not exceed 20 pounds.

### Fluid Ingress

Control Unit must meet fluid spillage resistance per IEC 60601-1 Cl. 44.3.

## Environmental

### Operating

1. Ambient Temperature: 10ºC to 40ºC
2. Relative Humidity: 30% to 70% (non-condensing)
3. Atmospheric Pressure: 525 mmHg to 795 mmHg (700-1060 hPa)

### Non-Operating

1. Ambient Temperature: -20ºC to 60ºC
2. Relative Humidity: 10% to 90%
3. Vibration/Shock: Per ISTA test procedure 3A.
4. Atmospheric Pressure: 375 mmHg to 795 mmHg (500-1060 hPa)

### Cleaning

The exterior surface of the control unit may be wiped down with any liquid disinfecting solution; non-flammable solution should be used whenever possible.

### Reliability

The system has a 2 year warranty.

## Regulatory

### Clearance and Markings

1. System requires 510(k) clearance.
2. System is intended for European distribution and must be CE marked.
3. System must be registered in other countries.

### Language Requirements

Initial Sales Release Units will include English and translations for German, Spanish, French, Italian, Swedish, Dutch, Portuguese, Danish, and Norwegian.

### Labels/Packaging/Operator’s Manual

Initial Sales Release Units will have applicable labeling and Operator’s Manual will be translated into German, Spanish, French, Italian, Swedish, Dutch, Portuguese, Danish, Norwegian, and Korean.