FLARE™ Assembly & Testing Documents: Volume 1

Version 2.0 (10/1/2011)

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Fluorescence-Assisted Resection and Exploration (FLARE™) Assembly & Testing Documents

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Fluorescence-Assisted Resection and Exploration (FLARE™) Assembly & Testing Documents

Mission Statement

Our mission is to solve important clinical problems
by applying first principles from chemistry and engineering.

The major focus of the laboratory is on
the development of imaging technology and contrast agents
to see cancer at its smallest possible manifestation.

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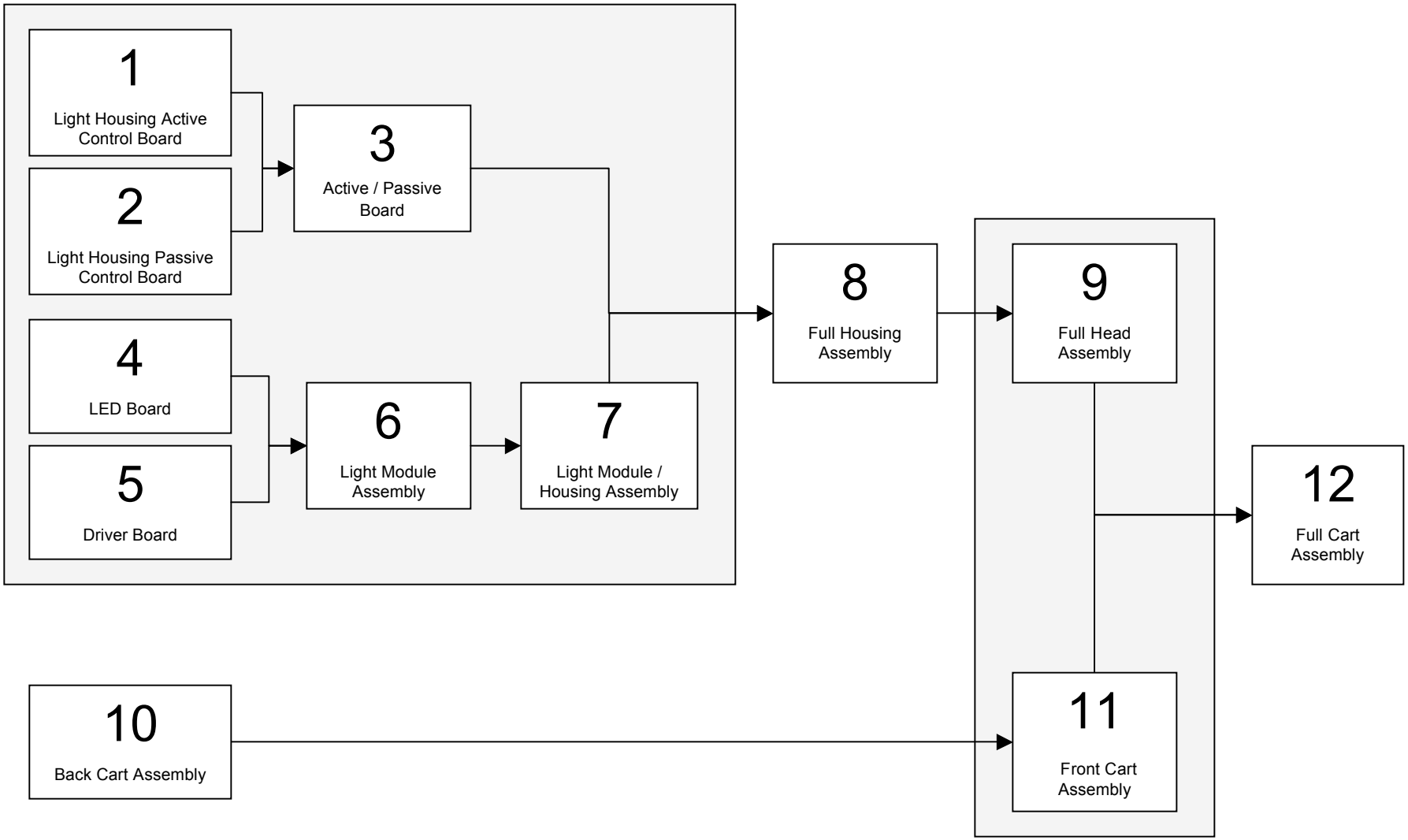
Version 2.0 (10/1/2011)

Macroview Assembly of FLARE™ System



Version 2.0 (10/1/2011)

Slide 1. Light Housing Active Control Board (ACB)

SOP A1-1: *Active Board*

BIDMC
- Ship most recent, approved version of design documents to Nashua Circuits according to SOP F1: *Shipping and Receiving*.

SOP F1: *Shipping and Receiving*
F1 Appendix A: *Shipping and Receiving*

Nashua Circuits
- Fabricates ACB from shipped materials
- Performs visual and electrical testing on site
- Ships fabricated ACB and unused components to BIDMC

BIDMC
- Fabricated ACB is received according to SOP F1: *Shipping and Receiving*.
- Visual testing is performed according to SOP T1-1: *Visual Inspection of Active Board 1*.

SOP F1: *Shipping and Receiving*
F1 Appendix A: *Shipping and Receiving Form*
SOP T1-1: *Visual Inspection of Active Board 1*
T1-1 Appendix A: *Active Board 1 Testing Form*

BIDMC
- Ship approved fabricated ACB, SOP A1-1 Appendix A: *Bill of Materials for Fabrication*, SOP A1-1 Appendix B: *Assembly Instructions*, and SOP A1-1 Appendix C: *Assembly Silk Screens* to Sure Design for assembly according to SOP F1: *Shipping and Receiving*.

SOP A1-1 Appendix A: *Bill of Materials*
SOP A1-1 Appendix B: Assembly Instructions
SOP A1-1 Appendix C: Assembly Silk Screens
SOP F1: *Shipping and Receiving*
F1 Appendix A Shipping and Receiving

Sure Design
- Assembles ACB from shipped materials
- Performs visual and electrical testing on site
- Ships assembled ACB and unused components to BIDMC

BIDMC
- Assembled ACB is received according to SOP F1: *Shipping and Receiving*.
- Testing is performed according to SOP T1-2: *Visual Inspection of Active Board 2* and SOP T2-1: *Short Testing for Active Board*.

SOP F1: *Shipping and Receiving*
F1 Appendix A: *Shipping and Receiving Form*
SOP T1-2: *Visual Inspection of Active Board 2*
T1-2 Appendix A: *Active Board 2 Testing Form*
SOP T2-1: *Short Testing for Active Board*
T2-1 Appendix A: *Active Board Short Testing Form*

Required SOPs
A1-1: Active Board
A1-1 Appendix A: Bill of Material
A1-1 Appendix B: Assembly Instructions
A1-1 Appendix C: Assembly Silk Screens
A2: Active Board Embedded Code Software
A2: Appendix A Specifications
F1: Shipping and Receiving
T1-1: Visual Inspection of Active Board 1
T1-2: Visual Inspection of Active Board 2
T2-1: Short Testing for Active Board
T3: Active Board

Required Forms
F1 Appendix A: Shipping and Receiving
T1-1 Appendix A: Active Board 1 Testing
T1-2 Appendix A: Active Board 2 Testing
T2-1 Appendix A: Active Board Short Testing
T3 Appendix A: Active Board Functional Testing

SOP A2: *Active Board Embedded Code Software*

BIDMC
- Load software on to active board according to SOP A2: *Active Board Embedded Code Software* and SOP A2 Appendix A: *Specifications*.

SOP A2 Appendix A: *Specifications*

BIDMC
- Control Board inspection

Functional 3: Temp sensors, DAQ on board, DAQ off chip, Communication with PC

T3 Appendix A Active Board Functional Testing

ACTIVE CONTROL BOARD

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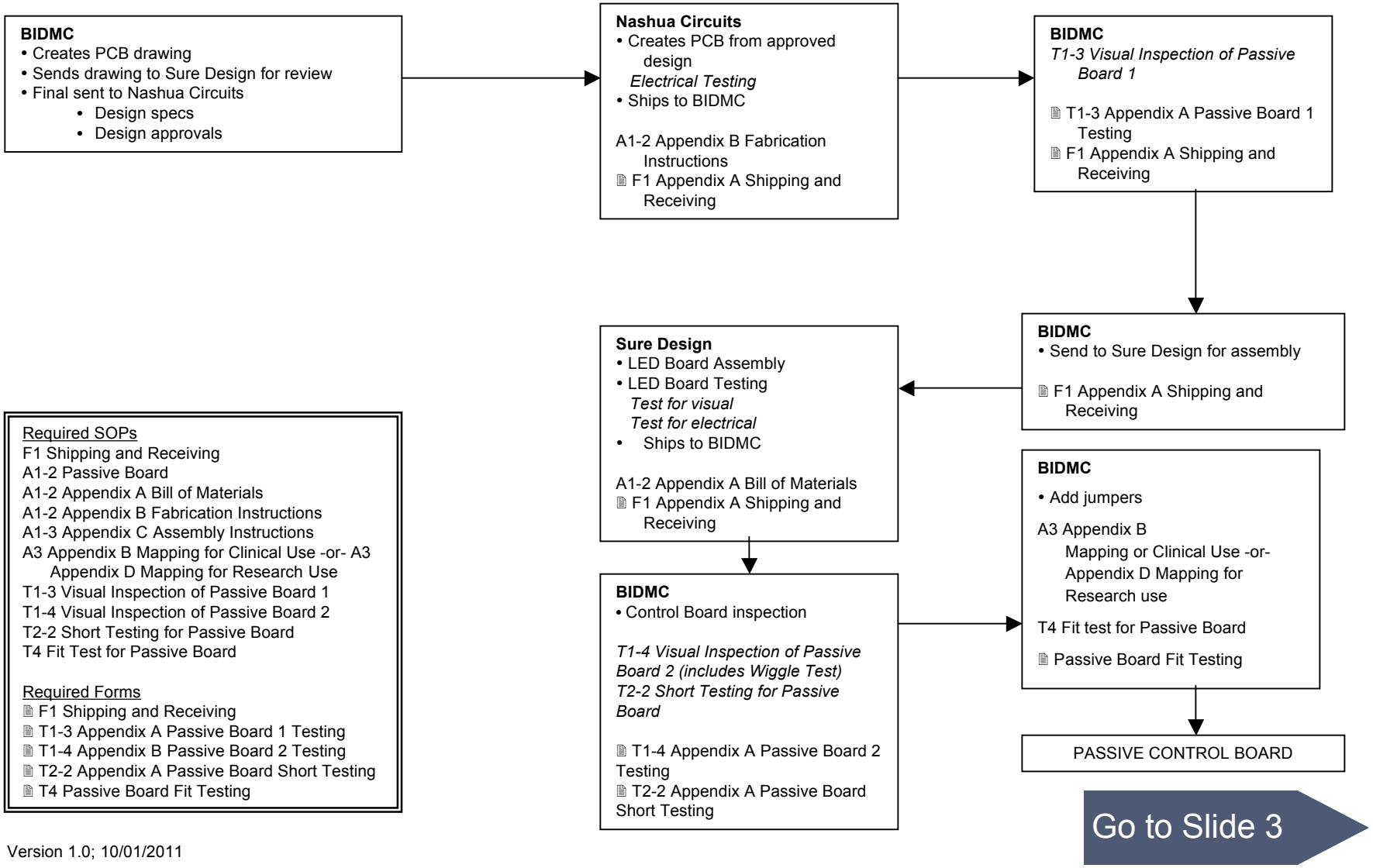
Slide 2. Light Housing Passive Control Board



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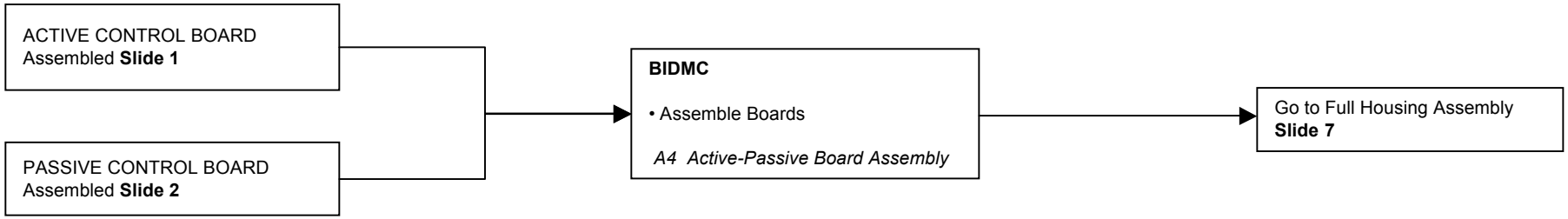
Slide 3. Active / Passive Control Board



Required SOPs
A4 Active-Passive Board Assembly

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Slide 4. LED Board Assembly

BIDMC
- Creates LED drawing
- Sends drawing to Sure Design for review
- Final sent to Nashua Circuits
  - Design specs
  - Design approvals

Nashua Circuits
- LED Board Fabrication
  Electrical Testing
- Ships to BIDMC

A1-4 Appendix B LED Board (v 1.2) Fabrication Instructions

A1-4 Appendix E Rebel LED Board (v 2.0) Fabrication Instructions

F1 Appendix A Shipping and Receiving

BIDMC
T1-5 Visual Inspection of LED Board 1

T1-5 Appendix A LED Board 1 Testing

BIDMC
- Sent to Sure Design for assembly

F1 Appendix A Shipping and Receiving

Sure Design
- LED Board Assembly
- LED Board Testing
  Test for visual
  Test for functional
- Ships to BIDMC

A1-4 Appendix A LED Board (v 1.2) Bill of Materials for Fabrication
A1-4 Appendix C LED Board (v 1.2) Assembly Instructions
A1-4 Appendix D Rebel LED Board (v 2.0) Bill of Materials
A1-4 Appendix F Rebel LED Board (v 2.0) Assembly Instructions

F1 Appendix A Shipping and Receiving

BIDMC
- LED Board inspection

T1-6 Visual Inspection of LED Board 2
T2-3 Short Testing for LED Board
T7 Leak Testing
T8 Functional Testing

T1-6 Appendix A LED Board 2 Testing
T2-3 Appendix A LED Board Short Testing
T7 Appendix A Leak Testing
T8 Appendix A Functional Testing

LED BOARD

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Required SOPs
F1 Shipping and Receiving
A1-4 LED Board
A1-4 Appendix A LED Board (v 1.2) Bill of Materials
A1-4 Appendix B LED Board (v 1.2) Fabrication Instructions
A1-4 Appendix C LED Board (v 1.2) Assembly Instructions
A1-4 Appendix D Rebel LED Board (v 2.0) Bill of Materials
A1-4 Appendix E Rebel LED Board (v 2.0) Fabrication Instructions
A1-4 Appendix F Rebel LED Board (v 2.0) Assembly Instructions
T1-5 Visual Inspection of LED Board 1
T1-6 Visual Inspection of LED Board 2
T2-3 LED Board Short Testing
T7 Leak Testing
T8 Functional Testing

Required Forms
F1 Appendix A Shipping and Receiving
T1-5 Appendix A LED Board 1 Testing
T1-6 Appendix A LED Board 2 Testing
T2-3 Appendix A LED Board Short Testing
T7 Leak Testing
T8 Functional Testing

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Slide 5. Driver Board

BIDMC
- Creates driver board drawing
- Sends drawing to Sure Design for review
- Final sent to Nashua Circuits
  - Design specs
  - Design approvals

Nashua Circuits
- Creates driver board according to specs and printed design

Electrical Testing
- Ships to BIDMC

A1-3 Appendix B Driver Board (v 3.0) Fabrication Instructions
A1-3 Appendix F Rebel Driver Board (v 4.1) Fabrication Instructions

F1 Appendix A Shipping and Receiving

BIDMC

T1-7 Visual Inspection of Driver Board 1

T1-7 Appendix A Driver Board 1 Testing

BIDMC
- Sent to Sure Design for assembly

F1 Appendix AShipping and Receiving

Sure Design
- Driver Board Assembly
- Driver Board Testing

Test for visual
Test for functional
- Ships to BIDMC

A1-3 Appendix A Driver Board (v 3.0) Bill of Materials
A1-3 Appendix C Driver Board (v 3.0) Assembly Instructions
A1-3 Appendix D Driver Board (v 3.0) Layout
A1-3 Appendix E Rebel Driver Board (v 4.1) Bill of Materials
A1-3 Appendix G Rebel Driver Board (v 4.1) Assembly Instructions
A1-3 Appendix H Rebel Driver Board (v 4.1) Layout

F1 Appendix A Shipping and Receiving

BIDMC
- Driver board inspection

T1-8 Visual Inspection of Driver Board 2
T8 Functional Testing

T1-8 Appendix A Driver Board 2 Testing
T8 Appendix A Functional Testing

DRIVER BOARD

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Required SOPs
F1 Shipping and Receiving
A1-3 Driver Board
A1-3 Appendix A Driver Board (v 3.0) Bill of Materials
A1-3 Appendix B Driver Board (v 3.0) Fabrication Instructions
A1-3 Appendix C Driver Board (v 3.0) Assembly Instructions
A1-3 Appendix D Driver Board (v 3.0) Layout
A1-3 Appendix E Rebel Driver Board (v 4.1) Bill of Materials
A1-3 Appendix F Rebel Driver Board (v 4.1) Fabrication Instructions
A1-3 Appendix G Rebel Driver Board (v 4.1) Assembly Instructions
A1-3 Appendix H Rebel Driver Board (v 4.1) Layout
T1-7 Visual Inspection of Driver Board 1
T1-8 Visual Inspection of Driver Board 2
T8 Functional

Required Forms
F1 Shipping and Receiving
T1-7 Appendix A Driver Board 1 Testing
T1-8 Appendix A Driver Board 2 Testing
T8 Functional Testing

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Slide 6. Light Module Assembly

LED Board
Assembled **Slide 4**

Driver Board
Assembled **Slide 5**

BIDMC
• LED Board and Driver board are assembled together

A5 Light Module Molding
T1-9 Visual Inspection of Light Module 1
T8 Functional
T9 Spectrometry
T10 Optical Fluence1
T11 Optical Fluence 2

• Send driver board to Albright

- F1 Appendix A Shipping and Receiving
- T1-9 Appendix A Light Module 1 Testing
- T8 Appendix A Functional Testing
- T9 Appendix A Spectometry Testing
- T10 Appendix A Optical Fluence 1 Testing
- T11 Appendix A Optical Fluence 2 Testing

Albright
• Molding per color requirement

A5 Appendix A Molding Fabrication/Assembly Instructions

BIDMC
T1-10 Visual Inspection of Light Module 2
T8 Functional
T9 Spectrometry
T10 Optical Fluence 1
T11 Optical Fluence 2

- F1 Appendix A Shipping and Receiving
- T1-10 Appendix A Light Module 2 Testing
- T8 Appendix A Functional Testing
- T9 Appendix A Spectometry Testing
- T10 Appendix A Optical Fluence 1
- T11 Appendix A Optical Fluence 2

LIGHT MODULE ASSEMBLY

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Required SOPs
F1 Shipping and Receiving
A5 Light Module Molding
A5 Appendix A Molding Fabrication/Assembly Instructions
T1-9 Visual Inspection of Light Module 1
T1-10 Visual Inspection of Light Module 2
T8 Functional
T9 Spectrometry
T10 Optical Fluence 1
T11 Optical Fluence 2

Required Forms
- F1 Appendix A Shipping and Receiving
- T1-9 Appendix A Light Module 1 Testing
- T1-10 Appendix A Light Module 2 Testing
- T8 Appendix A Functional Testing
- T9 Appendix A Spectrometry Testing
- T10 Appendix A Optical Fluence 1
- T11 Appendix A Optical Fluence 2

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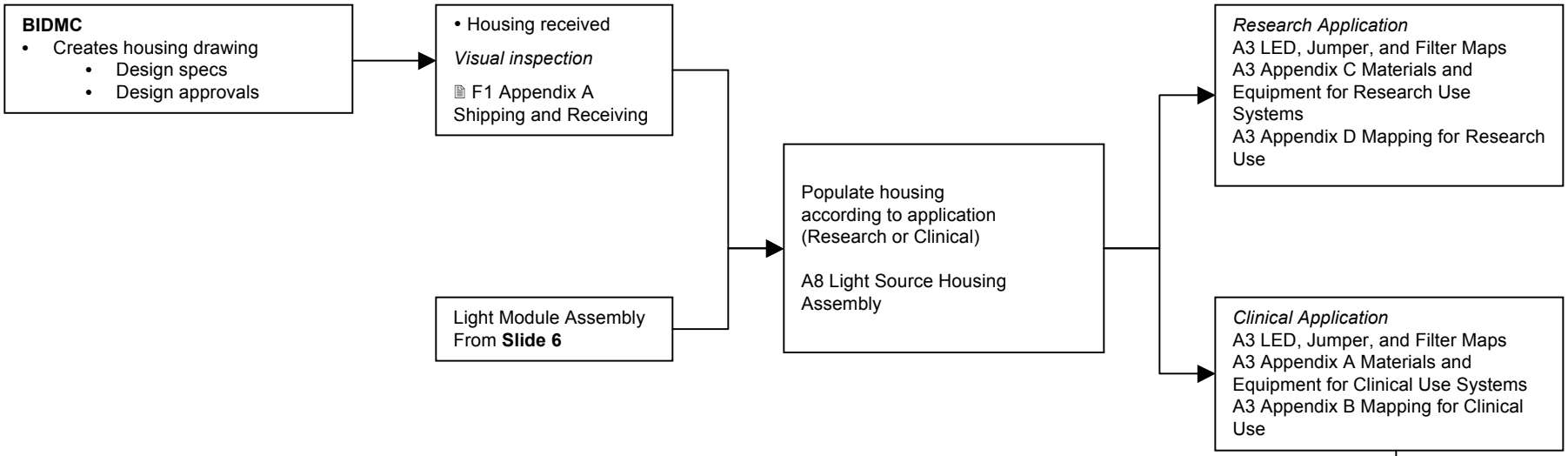
Slide 7. Light Module and Housing Assembly



Required SOPs
F1 Shipping and Receiving
A3 LED, Jumper, and Filter Maps

Clinical
A3 Appendix A Materials and Equipment for Clinical Use Systems
A3 Appendix B Mapping for Clinical Use

Research
A3 Appendix C Materials and Equipment for Research Use Systems
A3 Appendix D Mapping for Research Use

A8 Light Source Housing Assembly

Required Forms
F1 Appendix A Shipping and Receiving

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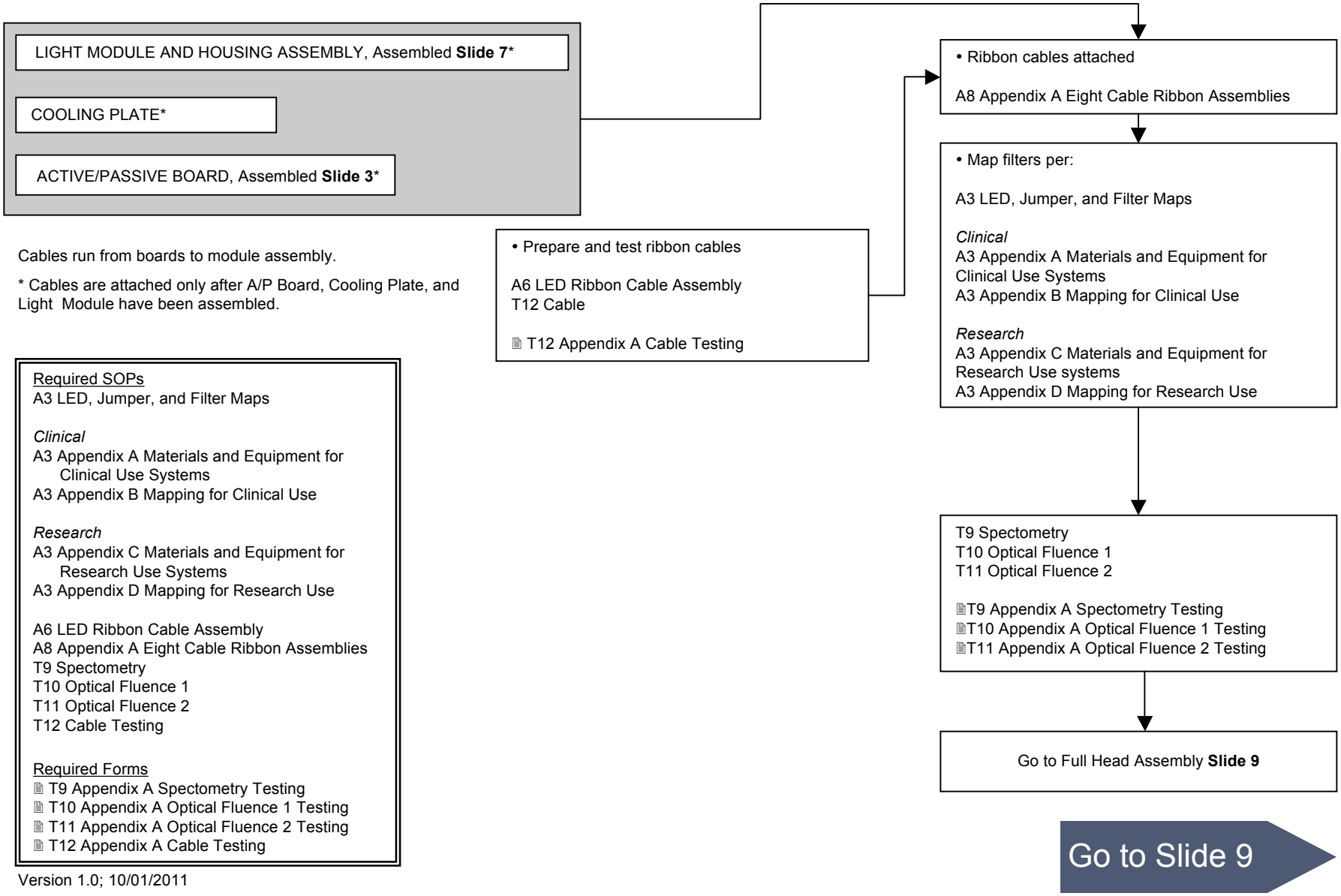
Slide 8. Full Head Assembly



Cables run from boards to module assembly.

* Cables are attached only after A/P Board, Cooling Plate, and Light Module have been assembled.

Required SOPs
A3 LED, Jumper, and Filter Maps

Clinical
A3 Appendix A Materials and Equipment for Clinical Use Systems
A3 Appendix B Mapping for Clinical Use

Research
A3 Appendix C Materials and Equipment for Research Use Systems
A3 Appendix D Mapping for Research Use

A6 LED Ribbon Cable Assembly
A8 Appendix A Eight Cable Ribbon Assemblies
T9 Spectometry
T10 Optical Fluence 1
T11 Optical Fluence 2
T12 Cable Testing

Required Forms
- T9 Appendix A Spectometry Testing
- T10 Appendix A Optical Fluence 1 Testing
- T11 Appendix A Optical Fluence 2 Testing
- T12 Appendix A Cable Testing

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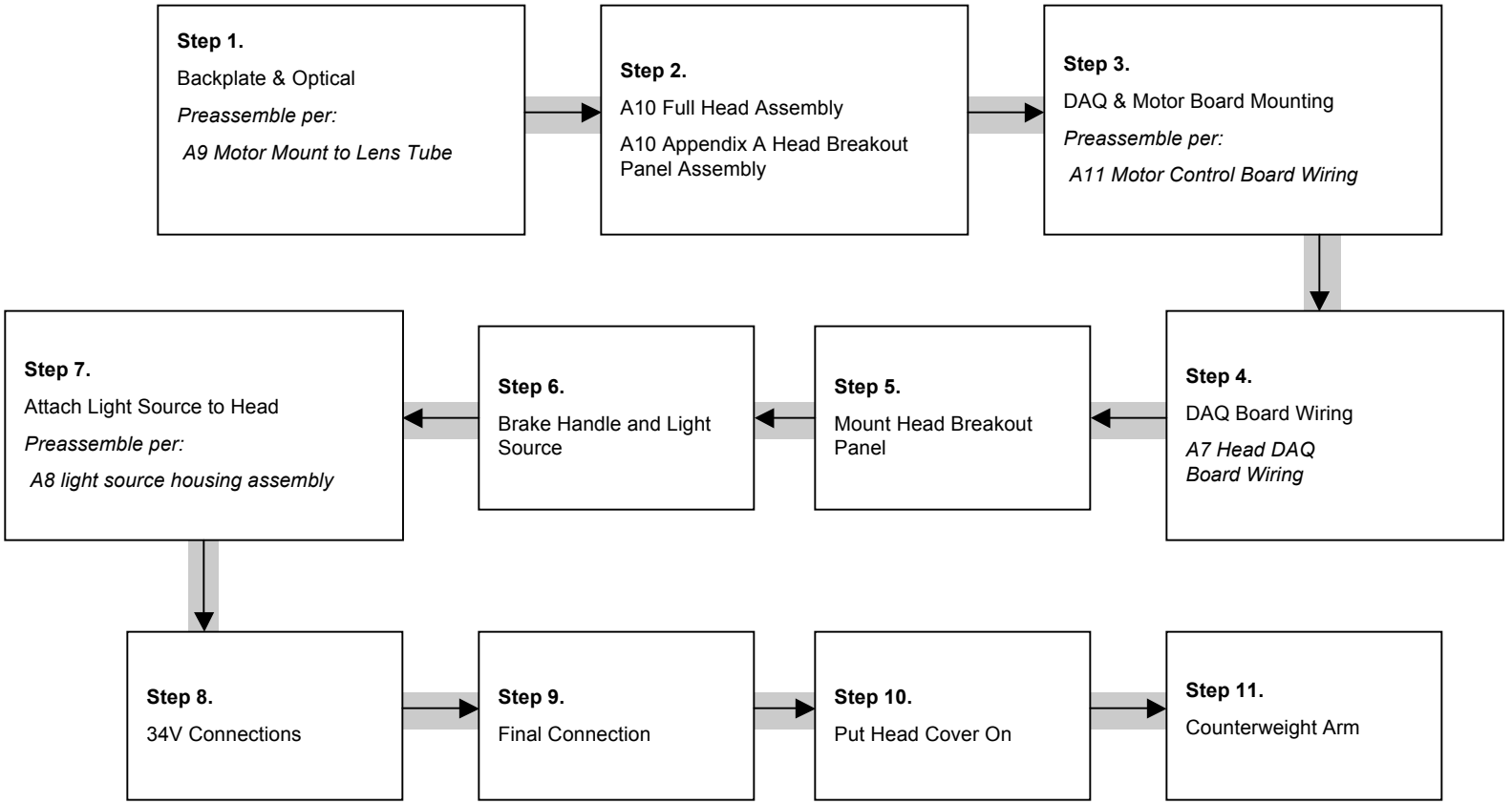
Slide 9. Full Head Assembly



Required SOPs

A9 Motor Mount to Lens Tube
A10 Full Head Assembly
A7 Appendix A Temperature Sensor Wiring
A7 Appendix C Passive Board to Breakout Panel Mapping
A11 Motor Control Board Wiring
A8 Light Source Housing Assembly
A7 Head DAQ Board Wiring
A7 Appendix B Passive Board Passive Board 20-pin Header Pinout
A10 Appendix A Head Breakout Panel Assembly

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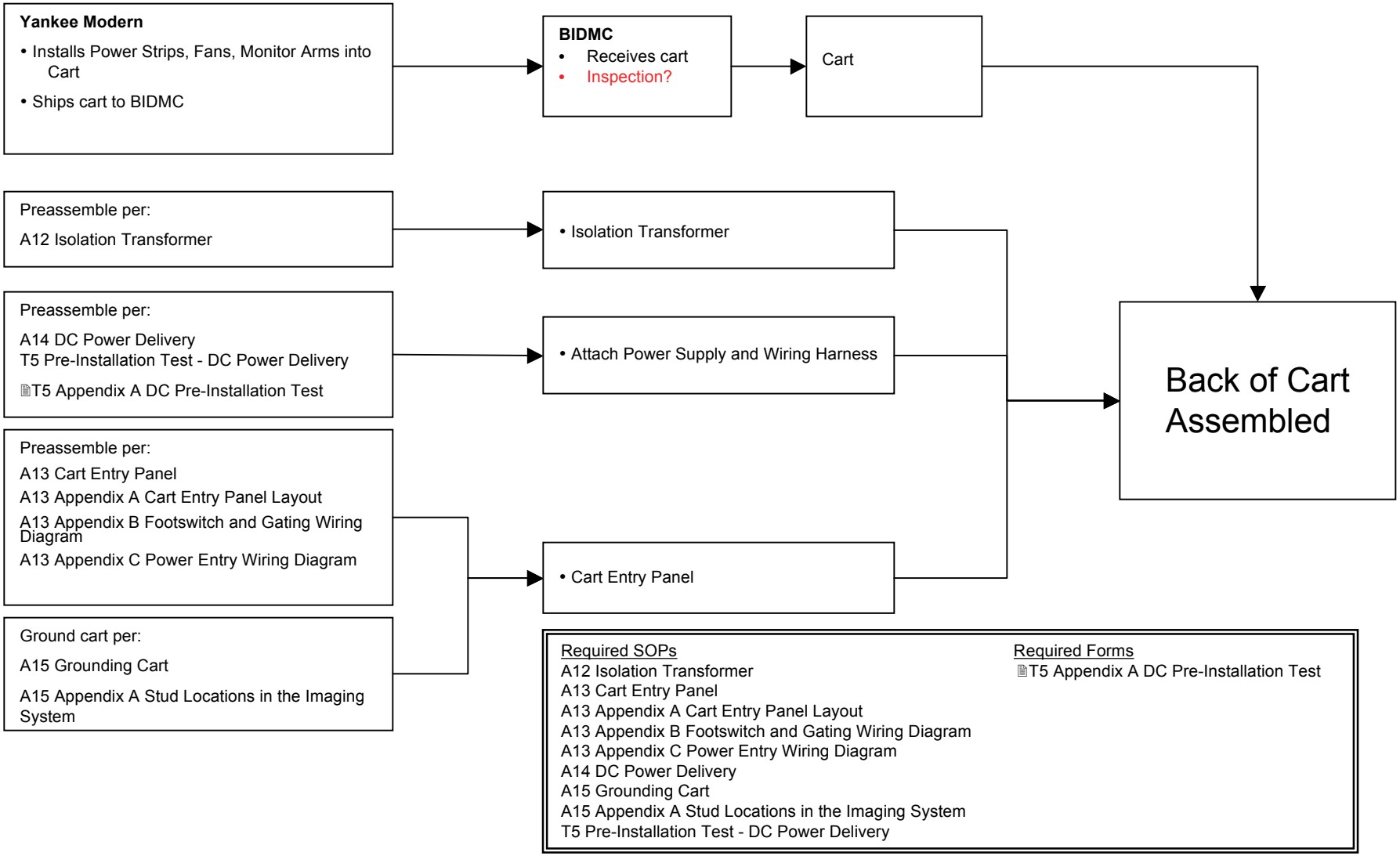
Slide 10. Cart Back Preassembly and Population



Required SOPs
A12 Isolation Transformer
A13 Cart Entry Panel
A13 Appendix A Cart Entry Panel Layout
A13 Appendix B Footswitch and Gating Wiring Diagram
A13 Appendix C Power Entry Wiring Diagram
A14 DC Power Delivery
A15 Grounding Cart
A15 Appendix A Stud Locations in the Imaging System
T5 Pre-Installation Test - DC Power Delivery

Required Forms
T5 Appendix A DC Pre-Installation Test

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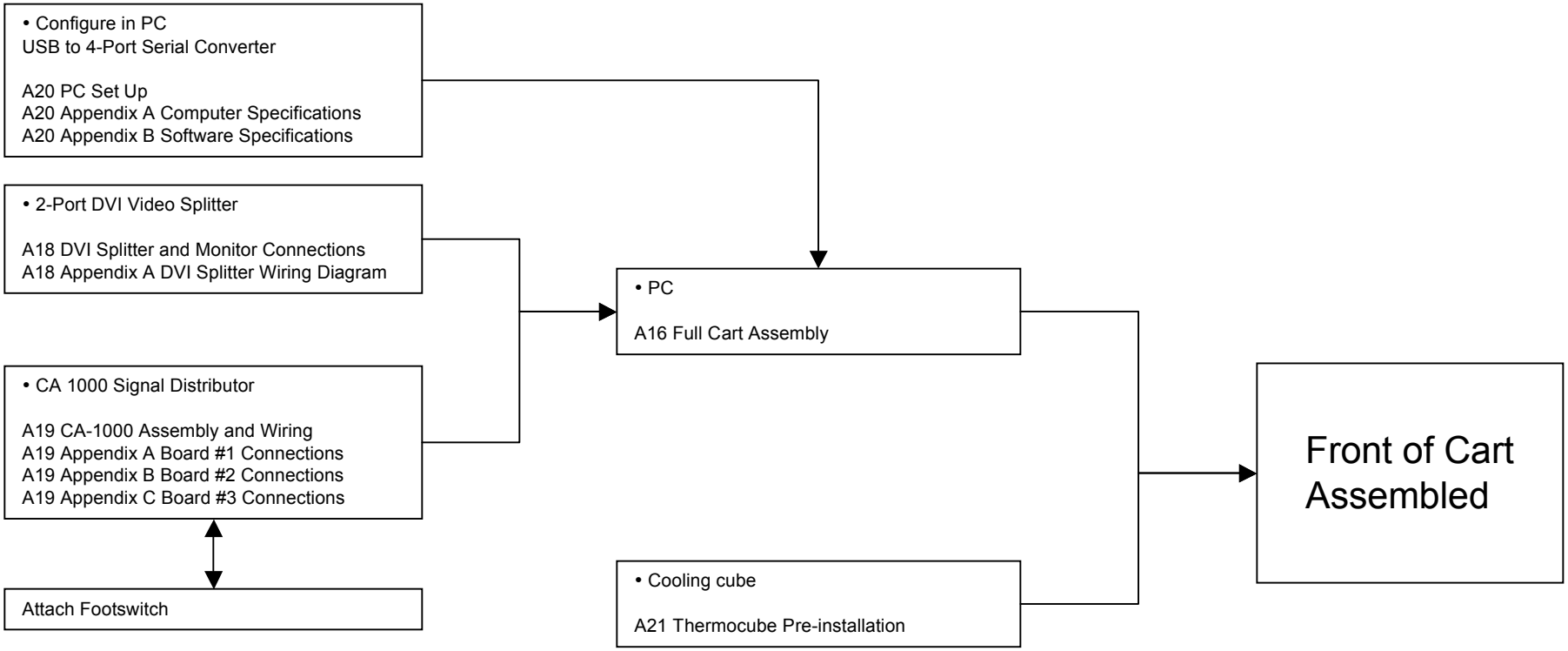
Slide 11. Cart Front Preassembly and Population



Required SOPs
A16 Full Cart Assembly
A18 DVI Splitter and Monitor Connections
A18 Appendix A DVI Splitter Wiring Diagram
A19 CA-1000 Assembly and Wiring
A19 Appendix A Board #1 Connections
A19 Appendix B Board #2 Connections
A19 Appendix C Board #3 Connections
A20 PC Set Up
A20 Appendix A Computer Specifications
A20 Appendix B Software Specifications
A21 Thermocube Pre-installation

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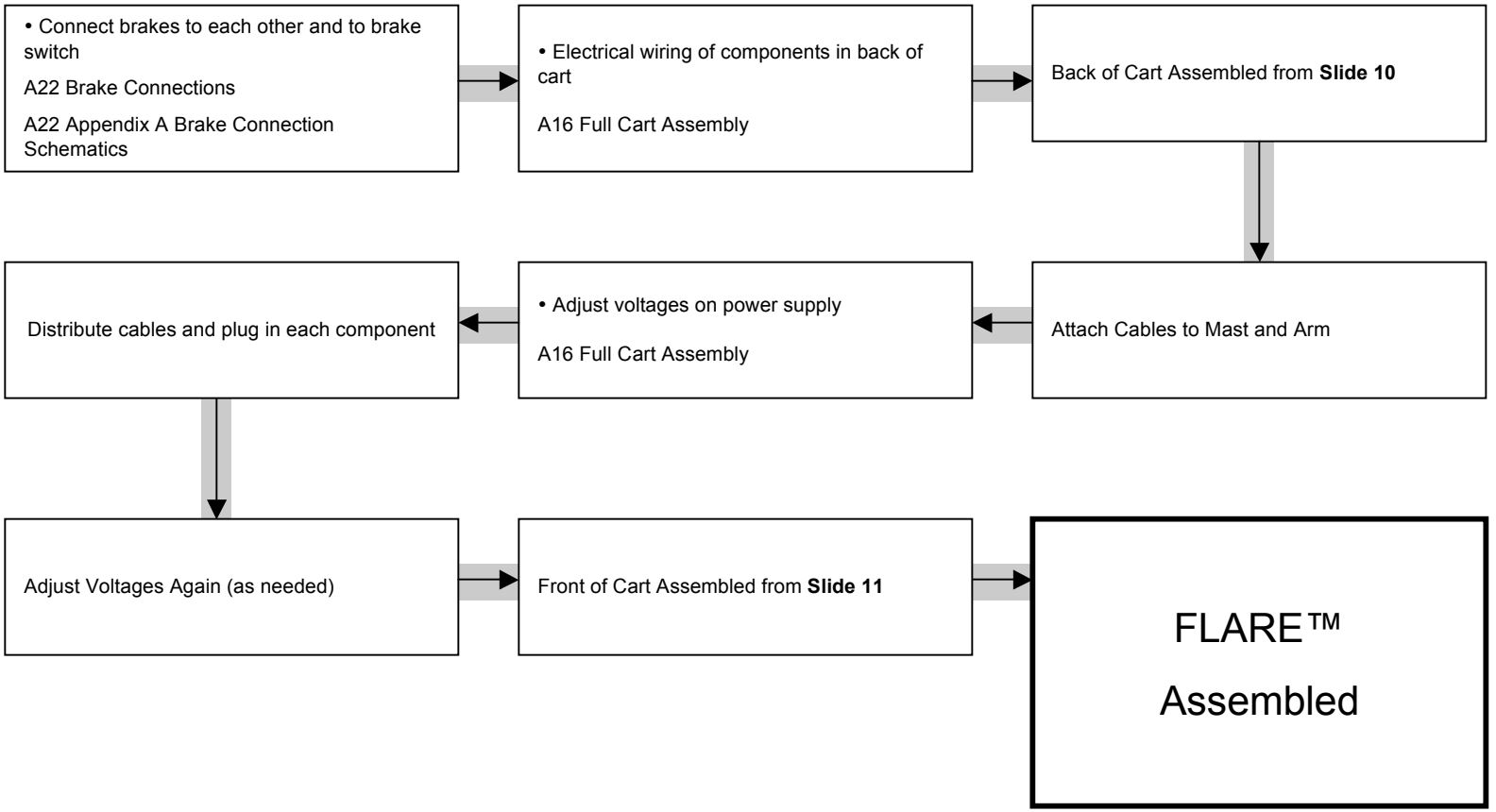
Slide 12. Full Cart Assembly



Required SOPs
A16 Full Cart Assembly
A22 Brake Connections
A22 Appendix A Brake Connection Schematics

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Slide 13. Assembled FLARE™ System Ready for Testing

Contact Information

Albright Technologies, Inc.	25 Litchfield Street Leominster, MA 01453 Phone: (978) 466-5870 Fax: (978) 466-5901 http://www.albright1.com/index.php
Nashua Circuits, Inc.	29 Crown Street Nashua, NH 03060 Phone: (603) 882-1773 Fax: (603) 883-8765 http://www.ncipcb.com/
PCB Express / Sunstone Circuits	13626 S. Freeman Road Mulino, OR 97042 Phone: (503) 829-9109 Fax: (503) 829-6657 www.pcbexpress.com
Sure Design	5027 Industrial Road, Unit 3 Farmingdale, NJ 07727 Phone: (732) 919-3066 Fax: (732) 919-3071 http://www.sure-design.com/
Yankee Modern Engineering	47 Town Forest Road Groton, MA 01450-1701 Phone: (978) 758-5847 Gordon@yankeemodern.com http://www.yankeemodern.com/

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-1
Active Board

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara Clough	06/10/2008		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A2 Active Board Embedded Code Software	T1-1 Visual Inspection of Active Board 1	F1 Shipping and Receiving
	T1-2 Visual Inspection of Active Board 2	A1-1 Appendix A
	T2-1 Short Testing for Active Board	A1-1 Appendix B
	T3 Active Board Functional Testing	A1-1 Appendix C

1. PURPOSE

The purpose of this document is to outline the procedures for fabrication and assembly of the Active Board used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel fabricating and assembling the Active Board for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

The following forms must be completed and kept in the master device file.

F1 Appendix A: *Shipping and Receiving Form*
T1-1 Appendix A: *Active Board 1 Testing Form*
T1-2 Appendix A: *Active Board 2 Testing Form*
T2-1 Appendix A: *Active Board Short Testing Form*

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

Most recent, approved version of design documents (Gerber Files and drawings)
SOP A1-1 Appendix A: *Bill of Materials*
SOP A1-1 Appendix B: *Assembly Instructions*
SOP A1-1 Appendix C: *Assembly Silk Screens*
SOP T1-1: *Visual Inspection of Active Board 1*
SOP T1-2: *Visual Inspection of Active Board 2*
SOP T2-1: *Short Testing for Active Board*

6. PROCEDURES

Steps
A. Ship the most recent, approved design documents (Gerber Files and drawings) to Nashua Circuits for fabrication. Ship materials according to SOP F1: *Shipping and Receiving.* **Form Required:** Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master device file. Attach any shipping paperwork to form.
B. Nashua Circuits produces the Active Board according to specifications and approved design, and performs visual and electrical testing on site. The fabricated Active Board is shipped back to the PI.
C. The fabricated Active Board is received at BIDMC according to SOP F1: *Shipping and Receiving*. **Form Required:** Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master device file. Attach any receipt paperwork to form.
D. Perform inspection as specified in SOP T1-1: *Visual Inspection of Active Board 1*. **Form Required**: Complete T1-1 Appendix A: *Active Board 1 Testing Form*; this form is to be kept in the master device file.
E. After passing inspection, ship the Active Board, associated components per and SOP A1-1 Appendix A: *Bill of Materials*, SOP A1-1 Appendix B: *Assembly Instructions*, and SOP A1-1 Appendix C: *Assembly Silk Screens* to Sure Design for assembly. Ship materials according to SOP F1: *Shipping and Receiving.* **Form Required:** Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master device file. Attach any shipping paperwork to form.
F. Sure Design assembles the Active Board according to specifications and performs visual and electrical testing on site. The approved assembled Active Board and all unused components are shipped back to the PI.
G. The assembled Active Board is received at BIDMC according to SOP F1: *Shipping and Receiving*. **Form Required:** Complete F1 Appendix A: *Shipping and Receiving Form*; this form is

to be kept in the master device file. Attach any receipt paperwork to form.

H. Perform visual inspection and functional testing as specified in SOP T1-2: *Visual Inspection of Active Board 2* and SOP T2-1: *Short Testing for Active Board.*

Forms Required: Complete T1-2 Appendix A: *Active Board 2 Testing Form* and T2-1 Appendix A: *Active Board Short Testing Form*; these forms are to be kept in the master device file.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for active board.	06/10/2008	Barbara Clough
V 1.0	Modified Record	Reformatted.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Edited and reformatted with Appendixes and additional forms.	10/01/2011	David Burrington Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-1 Appendix A
Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-1 Active Board	None	None

This Bill of Materials is for the assembly of the Active Board at Sure Design.

Table 1. Bill of Materials for Fabrication

Value	Qty	RefDefs	Description	Vendor	Part #
20 Ohm	10	R311, R411, R511, R611, R711, R717, R720, R724, R732, R736	1/8W 1% chip resistor	Panasonic	ERJ-6ENF20R0V
100 Ohm	1	R1	1/8W 5% chip resistor	Panasonic	ERJ-6GEYJ101V
150 Ohm	20	R31, R32, R41, R42, R51, R52, R61, R62, R71, R72, R312, R412, R512, R612, R712, R713, R714, R727, R730, R735	1/8W 1% chip resistor	Panasonic	ERJ-6ENF1500V
390 Ohm	2	R14, R15	1/4W 5% chip resistor	Panasonic	ERJ-8GEYJ391V
1 kOhm	1	R27	1/4W 5% chip resistor	Panasonic	ERJ-8GEYJ102V
1 kOhm	20	R35, R36, R39, R45, R46, R49, R55, R56, R59, R64, R65, R69, R74, R75, R79, R310, R410, R510, R610, R710	1/8W 1% chip resistor	Panasonic	ERJ-6ENF1001V
100 kOhm	2	R23, R24	1/4W 5% chip resistor	Panasonic	ERJ-8GEYJ104V
10 kOhm	2	R76, R77	1/8W 1% chip resistor	Panasonic	ERJ-6ENF1002V
499 Ohm	10	R718, R719, R721, R722, R725, R726, R729, R731, R733, R734	1/8W 1% chip resistor	Panasonic	ERJ-6ENF4990V
18pF	2	C9, C14	50V ceramic chip capacitor	Panasonic	ECJ-1VC1H180J
0.1 uF	11	C3, C11, C15-C18, C20-C21, C23, C25-C26	16V ceramic chip capacitor	Panasonic	ECJ-1VB1C104K
0.1 uF	10	C32, C34, C42, C44, C52, C54, C62, C63, C72, C73	25V ceramic chip capacitor	Murata Electronics	GRM31C5C1E104JA01L
0.1 uF	1	C1	50V ceramic chip capacitor	Panasonic	ECJ-2YB1H104K
0.1 uF	2	C29, C30	50V ceramic chip capacitor	Panasonic	ECJ-3VB1H104K
0.33 uF	3	C5, C6, C13	16V ceramic chip capacitor	Panasonic	ECJ-2YB1C334K
0.22 uF	2	C7, C8	16V ceramic chip capacitor	Panasonic	ECJ-3VB1C224K
0.47 uF	3	C12, C22, C24	16V ceramic chip capacitor	Panasonic	ECJ-2YB1C474K
10 uF	10	C31, C33, C41, C43, C51, C53, C61, C64, C71, C74	16V Tantalum capacitor	Rohm	TCA1C106m8R
150 uF	1	C27	20V Low ESR Tantalum TPS	AVX Corporation	TPSV157K020R0080
330 uF	1	C28	10V Low ESR Tantalum TPS	AVX Corporation	TPSD337K010R0100
22 uF	1	C35	22 uF Tantalum capacitor	Kemet	T520A226M006ATE100

Value	Qty	RefDefs	Description	Vendor	Part #
0.1 uF	10	C77, C78, C79, C82, C83, C84, C85, C86	0.1 uF capacitor	AVX Corporation	12065C104MAT2A
47 uH	2	L1, L2	47 uH 0.72A power conductor	J.W. Miller	PM54-470L-RC
-	2	D1, D4	Diode 1A 50V SMD MELF	Micro Commercial Components	DL4001-TP
-	2	D2, D3	LED Green Clear Lens 1206	Lumex	SML-LX1206GC-TR
-	1	D5	1A, 30V Schottky diode	ON Semiconductor	MBRS130T3G
-	1	D6	Diode Fast Switching SMD	Diodes, Inc.	LL4148-13
-	1	X1	22.1184 Quartz Crystal Thru	Citizen	HC49US22.11840592 MAI
-	1	U1	Mixed Signal Microcontroller	Texas Instruments	MSC1211Y5
-	3	U2, U3, U4	32-channel serially controlled3.5 Ohm 1.8V-5.5V±2.5V analog multiplexer	Analog Devices	ADG732BSUZ
-	1	U5	8 bit 10us DAC	Texas Instruments	TLC5628DW
-	1	U6	Multi-channel RS232 line driver	Texas Instruments	MAX3243CDBR
-	2	U7, U8	Single IC buffer driver with open	Texas Instruments	SN74LVC1G07DBVR
-	2	U9, U10	5V 1.5A Postitive voltage regulator	Texas Instruments	TL780-05CKTTR
-	1	U11	Supervisory circuit active high	Texas Instruments	TPS3837L30DBVT
-	1	U12	Supervisory circuit active low	Texas Instruments	TPS3838L30DBVT
-	2	U13, U14	Single inverter gate	Texas Instruments	SN74HC1G04DBVR
-	2	U15, U16	Single 2-input postive-OR gate	Texas Instruments	SN74AHC1G32DBVR
-	1	U17	(-5v) Low IQ DC-DC inverter	Maxim	MAX764CSA+
-	5	M3-M7	250 MHz 10ns multiplexer	Analog Devices	AD6174
-	5	X1, x3, x8, x9, x10	69 MHz Op Amp	Analog Devices	AD6397
-	2	SW2, SW4	Momentary Pushbutton Tact	Omron	B3F-1002
-	26	TP2, TP4-TP16, TP18-TP22, TTP0-TTP7	Miniature Test Point Terminal	Keystone Electronics	5000
-	2	B1, B4	2x17 header, 0.1” spacing	Samtec	SLW-117-01-G-D
-	2	B2, B3	2x15 header, 0.1” spacing	Samtec	SLW-115-01-G-D
-	6	JMP5, JMP6, JMP8,	1x3 header, 0.1” spacing	Samtec	TSW-103-07-L-S
-	3	TPG1-TPG3, TTP7	Multipurpose test point terminal	Keystone Electronics	5011
-	1	J1	1x8 header, 0.1” spacing	Samtec	TSW-108-07-L-S

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-1 Appendix A for SOP A1-1.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-1 Appendix B
Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-1 Active Board	None	None

These instructions are to be included in the assembly package for the manufactured components of the Active Board when it is shipped to Sure Design for assembly.

1. Silkscreen schematics have been included in the shipment; see A1-1 Appendix C: *Assembly Silk Screens.*

2. There is no silkscreen on the bottom of the board; see A1-1 Appendix C: *Assembly Silk Screens.*

3. TP17 - TP19 are labeled on the silkscreen bottom view; see A1-1 Appendix C: *Assembly Silk Screens.*

4. Use the yellow test point terminals for TTP0 - TTP6, and red terminals for TP2, TP4 - TP19.

5. X1 is a Quartz crystal; however, use connector sockets for the crystal and do not solder the crystal directly on the PCB. Only sockets are enclosed.

6. U11 and U12 have very close part numbers TPS3837 (versus TPS3838). Verify the part number prior to assembly.

7. The board-to-board connectors are soldered on the bottom side of the board (B1 - B4).

8. The ADG732 Multiplexers (U2, U3, U4) are very sensitive to ESD and heat. Use extra care when soldering them.

9. Pin 1 of the ICs has been shown either by a number “1” next to the pin or a white circle. Note the designated symbol when soldering the ICs.

10. Positive and negative pins of the capacitors and diodes have been marked with “+” and “–“ on the PCB. Use extra care to use the correct pin when applicable.

11. Many capacitors and resistors have similar footprints. Use extra care to select the correct component when soldering.

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-1 Appendix B for SOP A1-1.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-1 Appendix C
Assembly Silk Screens

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-1 Active Board	None	None

These silk screens are to be included in the assembly package for the manufactured components of the Active Board when it is shipped to Sure Design for assembly.

Figure 1. Active Board Assembly Bottom: Full View

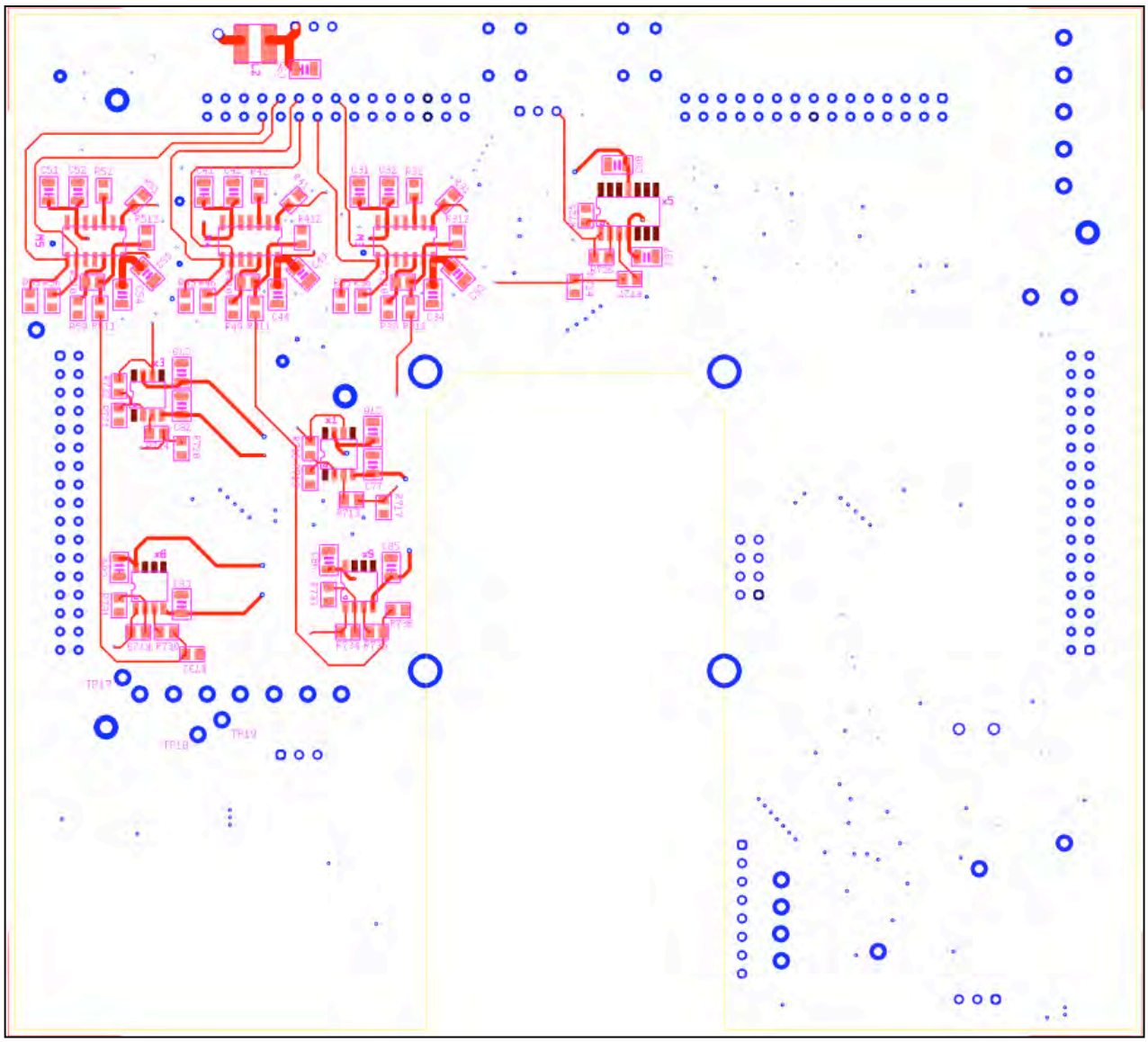
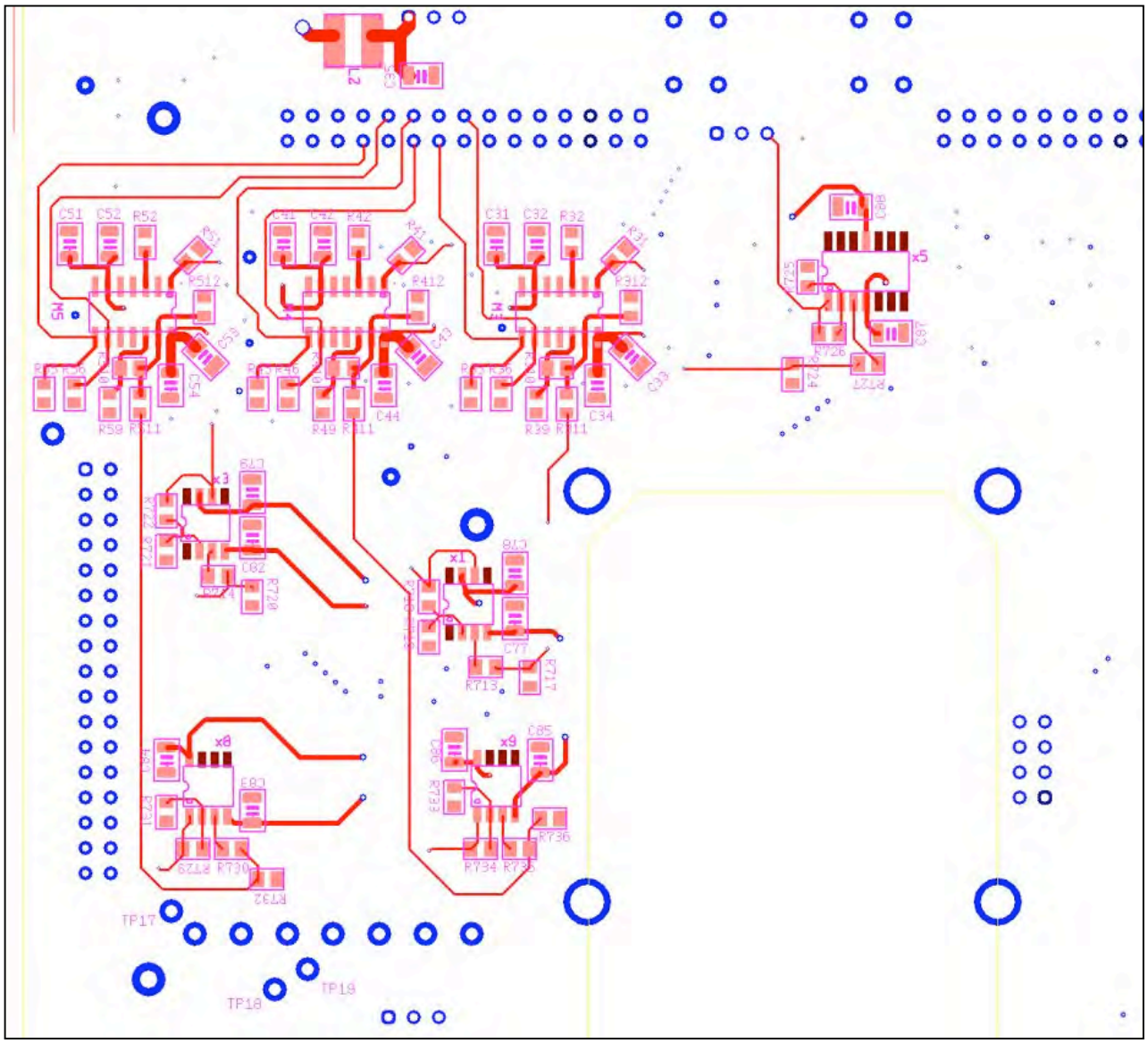


Figure 2. Active Board Assembly Bottom: Close Up View



Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-1 Appendix C for SOP A1-1.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-2
Passive Board

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara Clough Alan Stockdale	04/14/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	T1-3 Visual Inspection of Passive Board 1	F1 Shipping and Receiving
	T1-4 Visual Inspection of Passive Board 2	A1-2 Appendix A
	T4 Fit Test for Passive Board	A1-2 Appendix B
		A1-2 Appendix C

1. PURPOSE

The purpose of this document is to outline the procedures for fabrication and assembly of the Passive Board used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel fabricating and assembling the Passive Board for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

The following forms must be completed and kept in the master device file.

F1 Appendix A: *Shipping and Receiving Form*
T1-3 Appendix A: *Passive Board 1 Testing Form*
T1-4 Appendix A: *Passive Board 2 Testing Form*
T4 Appendix A: *Passive Board Fit Testing Form*

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

Most recent, approved version design documents (Gerber Files and drawings)
A1-2 Appendix A: *Bill of Materials for Fabrication*
A1-2 Appendix B: *Fabrication Instructions*
A1-2 Appendix C: *Assembly Instructions*

6. PROCEDURES

Steps
A. Ship the most recent, approved design documents (Gerber Files and drawings) to Nashua Circuits for fabrication. **Form Required:** Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master device file.

B. Nashua Circuits produces the Passive Board according to specifications and approved design, and performs testing on site. The approved fabricated Passive Board is shipped back to the PI.

C. To receive the fabricated Passive Board, complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master file. Attach receipt paperwork to form.

Form Required: Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master device file.

D. Perform visual inspection and functional testing as specified in SOP T1-3 Visual Inspection of Passive Board 1.

Form Required: Record the results of inspection and testing in T1-3: *Passive Board 1 Testing Form*; this form is to be kept in the device master file.

E. After passing inspection and testing, ship the Passive Board, associated components, SOP A1-2 Appendix A: *Bill of Materials*, and SOP A1-2 Appendix C: Assembly Instructions to Sure Design for assembly.

Form Required: Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master file.

F. Sure Design assembles the Passive Board according to specifications and performs testing on site. The approved assembled Passive Board and all unused components are shipped back to the PI.

G. To receive the assembled Passive Board, complete F1: *Shipping and Receiving Form*; this form is to be kept in the master file. Attach receipt paperwork to form.

Form Required: Complete F1 Appendix A: *Shipping and Receiving Form*; this form is to be kept in the master file.

H. Perform visual inspection and functional testing as specified in SOP T1-4: *Visual Inspection of Passive Board 2* and SOP T4: *Fit Test for Passive Board.*

Form Required: Record the results of inspection and testing in T1-4 Appendix A: *Passive Board 2 Testing Form* and T4: *Passive Board Fit Testing Form*; these forms are to be kept in the device master file.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Passive Board fabrication.	04/14/2009	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Reformatted.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Edited and reformatted with Appendixes and additional forms.	10/01/2011	Lorissa Moffitt David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-2 Appendix A
Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-2 Passive Board	None.	A1-2 Appendix B

This Bill of Materials is for the assembly of the Passive Board at Sure Design.

Table 1. Bill of Materials for Assembly

Value	Qty	RefDefs	Description	Vendor	Part #
	2	x1, x2	PCB terminal Block 5.08 mm pitch	Phoenix Contact	MKKDS 1.5 / 2-5.08
	2	B1, B4	2 x 17 header, 0.1" spacing	Samtec	MTLW-117-06-G-D-110
	2	B2, B3	2 x 15 header, 0.1" spacing	Samtec	MTLW-115-06-G-D-110
	4	U1-U4	2 x 30 header, 0.1" spacing	Tyco	1-1761605-6
	4	U5-U8	2 x 20 header, 0.1" spacing	Tyco	5103310-8
	76	U12-U87	2 x 5 low profile header, 0.1" spacing	Samtec	MTLW-105-05-T-D-180
	76	U88-U163	1 x 3 low profile header, 0.1" spacing	Samtec	MTLW-103-05-T-S-180
	1	U166	* 2 x 10 mini-power terminal strip, 0.1" spacing	Samtec	IPL1-110-01-S-D
1000uF	2	C1, C2	25v Electrolytic Radial Capacitor, ±20%	Panasonic	ECA-1EHG102
470 uF	1	C3	35v Electrolytic Radial Capacitor, ±20%	Panasonic	ECA-1VHG471
100 uF	1	C4	10v Electrolytic Radial Capacitor, ±20%	Panasonic	ECA-1AHG100
1 kOhm	76	R1-R76	1206 Thick Film Chip Resistors ¼ watt 1.0Kohms 1%	Vishay	CRCW12061K00FKEA

* The layout has 24 pins; however, the supplied connectors has only 20 so the first 20 pins should be used

.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-2 Appendix A Bill of Materials for SOP A1-2 Passive Board.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-2 Appendix B
Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-2 Passive Board	None.	None

These instructions are to be included in the fabrication package for the Passive Board when it is shipped to Nashua Circuits for fabrication.

1. This board has two power planes (24v and 5v) and two GND planes. To minimize the warping of the board, a thicker board size, i.e. 0.93", is used.

2. Use 2 ounce copper on this board.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-2 Appendix B Fabrication Instructions for SOP A1-2 Passive Board.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-2 Appendix C
Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-2 Passive Board	None.	A1-2 Appendix A

These instructions are to be included in the assembly package for the Passive Board when it is shipped to Sure Design for assembly.

1. On the center top of the board, the footprint indicates the need for a 24-pin component (U166); however, a 20-pin black header has been supplied. Use holes labeled 1 through 20 for the header.

> **Note:** Use extra care for placement of the notch on the header; it should face outside the board.

2. In a previous assembly of the Passive Board, there was a short from line C2 (Connector B3: Pin16) to ground. Test for a short after soldering, and verify that C1 through C5 (on B3 as well) are not shorted to ground.

3. This version of the board has 76 SMD resistors that mount on the bottom side of the board. Do not forget to include them.

4. Use extra care regarding the +/– leads of the capacitors.

5. The 3-pin and 2×5 (10-) pin headers have tiny little pegs on their bottom side; use extra care with their placement on the board (see Figures 1 and 2).

Figure 1. Pegs on the lower side of pin headers.

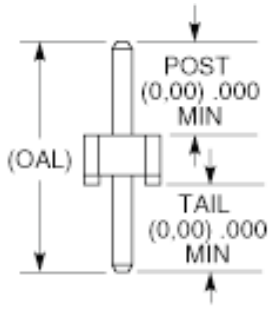


Figure 2. Orientation for placement of header.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-2 Appendix C Assembly Instructions for SOP A1-2 Passive Board.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3
Driver Board

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara Clough Alan Stockdale	04/14/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	T1-7 Visual Inspection of Driver Board 1	A1-3 Appendix A
	T1-8 Visual Inspection of Driver Board 2	A1-3 Appendix B
	T8 Functional Testing	A1-3 Appendix C
		A1-3 Appendix D
		A1-3 Appendix E

		A1-3 Appendix F
		A1-3 Appendix G
		A1-3 Appendix H
		F1 Shipping and Receiving

1. PURPOSE

The purpose of this document is to outline the procedures for fabrication and assembly of the Driver Board used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel fabricating and assembling the Driver Board for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

The following forms must be completed and kept in the master device file.

F1 Appendix A Shipping and Receiving Form
T1-7 Appendix A Visual Inspection of Driver Board 1
T1-8 Appendix A Visual Inspection of Driver Board 2
T8 Functional Testing Form

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

Most recent, approved version design documents (Gerber Files and drawings)
A1-3 Appendix A Driver Board (v 3.0) Bill of Materials
A1-3 Appendix B Driver Board (v 3.0) Fabrication Instructions
A1-3 Appendix C Driver Board (v 3.0) Assembly Instructions
A1-3 Appendix D Driver Board (v 3.0) Layout
A1-3 Appendix E Rebel Board (v 4.1) Bill of Materials
A1-3 Appendix F Rebel Board (v 4.1) Fabrication Instructions
A1-3 Appendix G Rebel Board (v 4.1) Assembly Instructions

A1-3 Appendix H Rebel Board (v 4.1) Layout

6. PROCEDURES FOR DRIVER BOARD (V 3.0)

Steps	
A. Ship the most recent, approved design documents (Gerber Files and drawings) and A1-3 Appendix B to Nashua Circuits for fabrication. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
B. Nashua Circuits produces the Driver Board according to specifications and approved design, and performs testing on site. The approved fabricated driver board is shipped back to the PI.	-
C. To receive the fabricated Driver Board, complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
D. Perform visual inspection and functional testing as specified in SOP T1-7 Visual Inspection of Driver Board 1. Form Required: Complete T1-7 Appendix A Driver Board 1 Testing Form; this form is to be kept in the master device file.	
E. After passing inspection and testing, ship the Driver Board, associated components with A1-3 Appendix A, A1-3 Appendix C, and A1-3 Appendix D to Sure Design for assembly. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
F. Sure Design assembles the Driver Board according to specifications and performs testing on site. The approved assembled passive board and all unused components are shipped back to the PI.	-
G. To receive the assembled Driver Board, complete	

A1-3 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
H. Perform visual inspection and functional testing as specified in SOP T1-8 Visual Inspection of Driver Board 2 and T8 Functional Testing respectively. Form Required: Complete T1-8 Visual 8 Testing and T8 Functional Testing Forms; these forms are to be kept in the master device file.	

7. PROCEDURES FOR REBEL DRIVER BOARD (V 4.0)

Steps	
I. Ship the most recent, approved design documents (Gerber Files and drawings) and A1-3 Appendix F to Nashua Circuits for fabrication. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
J. Nashua Circuits produces the Rebel Driver Board according to specifications and approved design, and performs testing on site. The approved fabricated driver board is shipped back to the PI.	-
K. To receive the fabricated Rebel Driver Board, complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
L. Perform visual inspection and functional testing as specified in SOP T1-7 Visual Inspection of Driver Board 1. Form Required: Complete T1-7 Driver Board 1	

Testing Form; this form is to be kept in the master device file.	
M. After passing inspection and testing, ship the Rebel Driver Board, associated components and A1-3 Appendix E, A1-3 Appendix G, and A1-3 Appendix H to Sure Design for assembly. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
N. Sure Design assembles the Rebel Driver Board according to specifications and performs testing on site. The approved assembled passive board and all unused components are shipped back to the PI.	-
O. To receive the assembled Rebel Driver Board, complete A1-3 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
P. Perform visual inspection and functional testing as specified in SOP T1-8 Visual Inspection of Driver Board 2 and T8 Functional Testing, respectively. Form Required: Complete T1-8 Driver Board 2 Testing and T8 Functional Testing Forms; these forms are to be kept in the master device file.	

8. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Driver Board fabrication and assembly.	04/14/2009	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Edited.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix A
Driver Board (v 3.0) Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0	None	None

This Bill of Materials is for the assembly of the Driver Board (v 3.0) at Sure Design

Table 1: Driver Board (Version 3.0)

Value	Ref Def #	Qty.	Manufacturer	Part #
2x3pin header SMT	U30	1	Tyco	2-1761603-1
1uF-capacitor	C5	1	Taiyo Yuden	GMK212B7105KG-T
2.00 Kohm-resistor SMT	R2, R3, R9, R10	4	Yageo	RT0603DRD072KL
47.0 ohm—resistor SMT	R6	1	Susumu Co.	RG1608P-470-B-T5
10.0 ohm—resistor SMT	R5, R12	2	Susumu Co.	RL1220S-100-F
2 pin header	U19, U27, U28	3	Samtec	MTLW-102-24-L-S-300
100 ohm—resistor SMT	R1, R4, R8, R11	4	Yageo	RT0603DRD07100RL
100nF-SMT0805	C1, C2, C3, C4, C6	5	Kemet	C0805C104K5RACTU
523 ohm-resistor SMT	R7	1	Susumu Co.	RG1608P-5230-B-T5
MAX4451 IC SMT	U1	1	Maxim	MAX4451ESA+-ND
TempSensor IC SMT	U5	1	Nat. Semicond.	LM50CIM3/NOPB
ZVN3306F IC SOT23	U2, U4	2	Zetex	ZVN3306FTA

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix A Driver Board (v 3.0) Bill of Materials for SOP A1-3 Driver Board.	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix B
Driver Board (v 3.0) Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0	None	None

These instructions are to be included in the fabrication package for the Driver Board (v 3.0) when shipped to Nashua Circuits for fabrication.

1. All files provided: Gerber files for top and bottom sides: Copper, Silkscreen, Paste mask, Board outline, Drill mask, and Drill file.
2. Paste mask will be provided by the Frangioni Laboratory, stepped by Nashua Circuits, and sent to Sure Design.
3. Thickness of board: 4 layers, 0.062".
4. Key dimensions: Final board is circular 26.5 mm ± 0.005" (± 0.127 mm) in diameter, but will be manufactured in a pallet fashion to assist Sure Design with soldering.
5. Boards need to be clean from any contamination.
6. Pallets are checked (NRE) by Nashua Circuits.
7. Pallets are pre-cut by Nashua Circuits.
8. Metal "pour": Standard 1 oz. (= 0.0014" = 0.036 mm), which ends up on the board as 2X = 2 oz. = 0.0028" = 0.072 mm).
9. Color of Mask: Black.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix B Driver Board (v 3.0) Fabrication for SOP A1-3 Driver Board.	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix C
Driver Board (v 3.0) Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

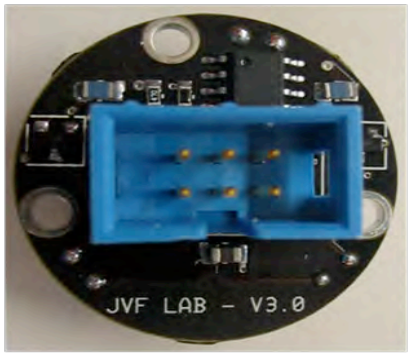
Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

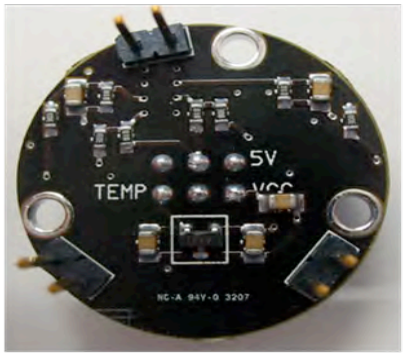
Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0	None	A1-3 Appendix A
		A1-3 Appendix B

These instructions are to be included in the assembly package for the Driver Board (v 3.0) when shipped to Sure Design for assembly.

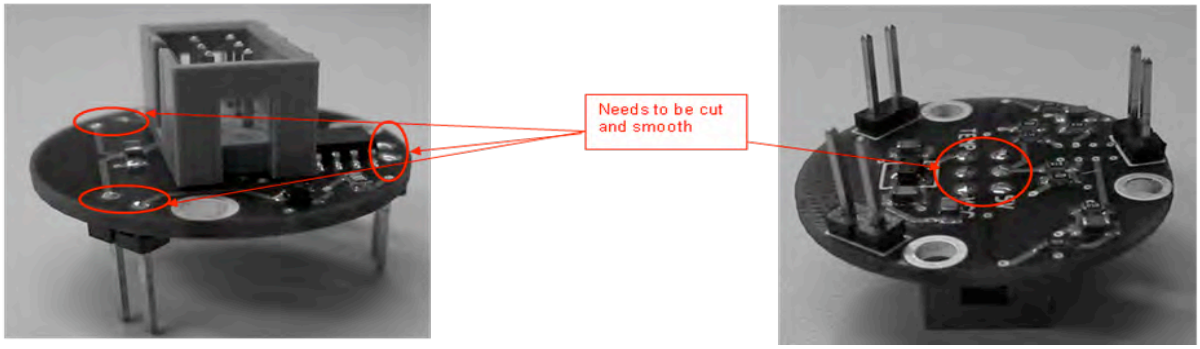
1. Driver boards need to be smooth and round without bumps.
2. ICs will be soldered using over soldering.
3. Stepped mask is provided by Nashua Circuits to Sure Design; the stencil mask will be made from it.
4. Boards need to be clean from any contamination.
5. Proper electrostatic mitigation needed for sensitive ICs.
6. The top of the 2-pin headers need to be cut.
7. All through-board soldering (2-pin and 6-pin headers) needs to be smooth to avoid sharp edges (see figures).
8. Boards will be visually inspected after assembly. Special attention should be paid to the above-mentioned features.
9. Assembly instructions are provided by BIDMC in these fabrication notes.
10. Special attention should be paid to protecting boards during shipment.

Aspect of Final Board:





Sharpness of through-hole components:



Driver Board – Version 3.0

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix C Driver Board (v 3.0) Assembly Instructions for Sure Design for SOP A1-3 Driver Board.	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix D
Driver Board (v 3.0) Layout

Version 0

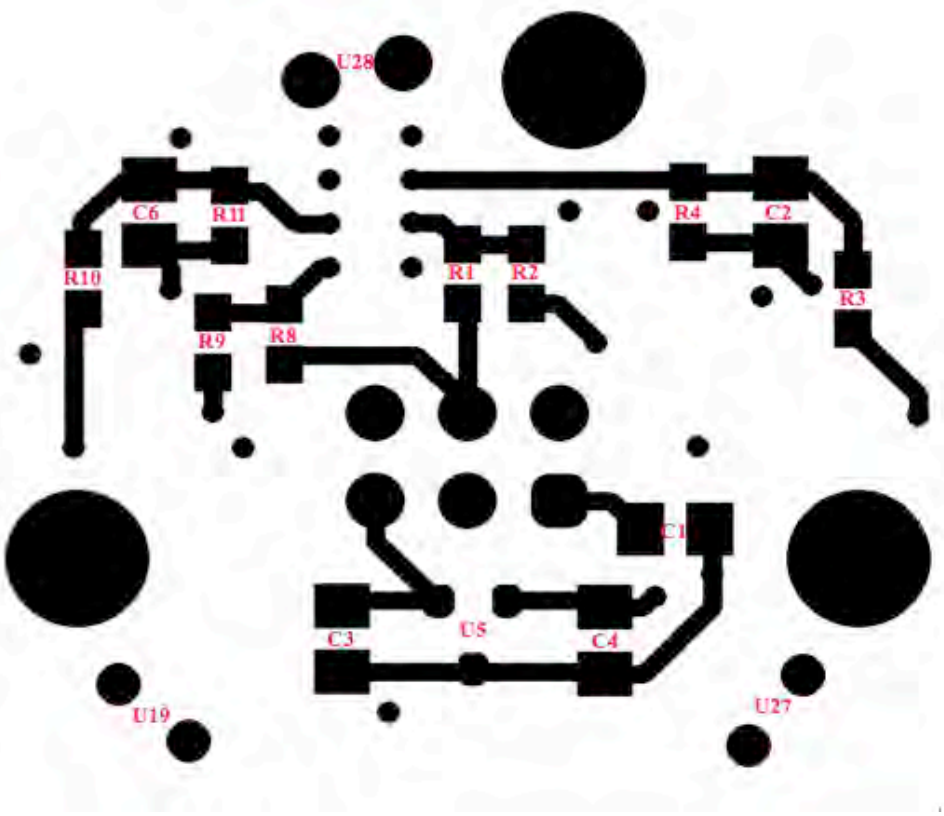
Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0	None	A1-3 Appendix C

Driver Board (v 3.0) – Layout

Top



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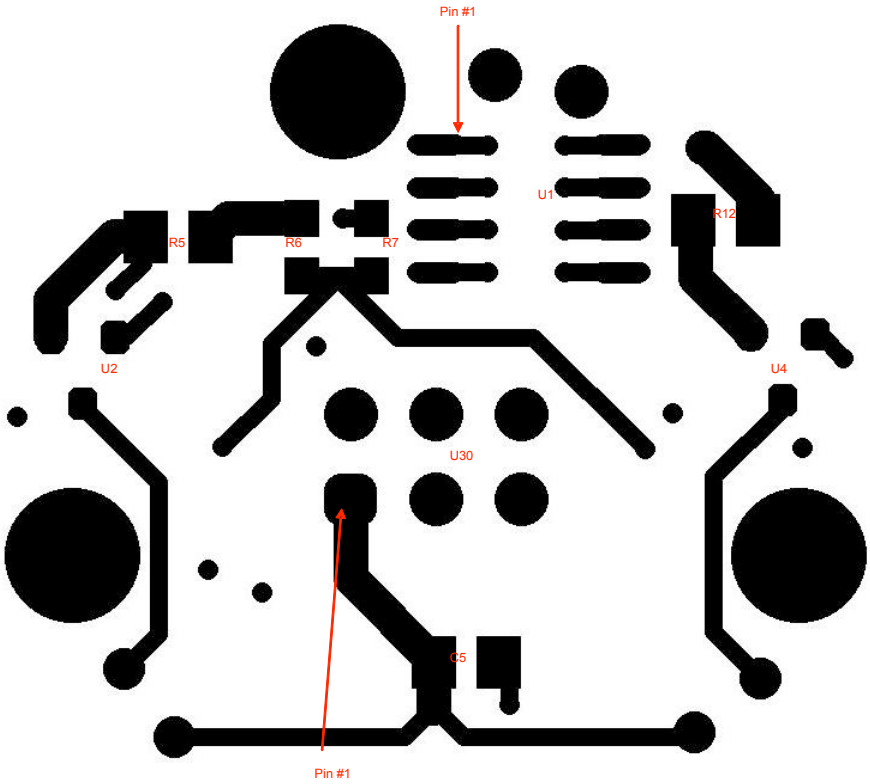
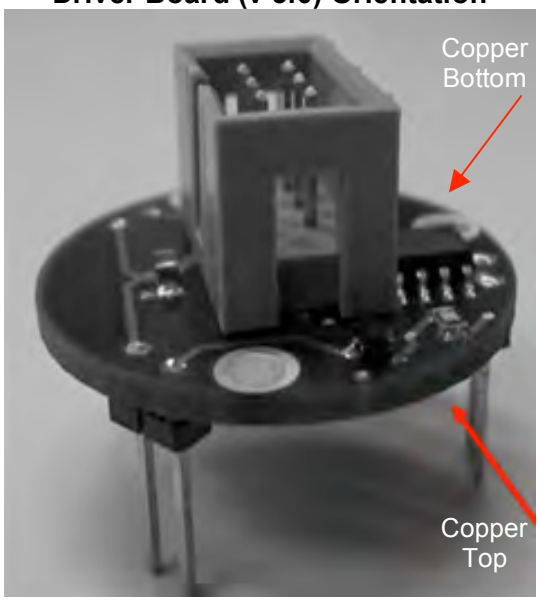


Driver Board (v 3.0) Orientation



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix D Driver Board (v 3.0) Layout for SOP A1-3 Driver Board.	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix E
Rebel Driver Board (v 4.1) Bill of Materials

Version 0

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 3.0		

This Bill of Materials is for the assembly of the Rebel Driver Board (v 4.1) at Sure Design.

Table 1: Rebel Driver Board (Version 4.1)

VALUE	Ref Def #	SHAPE	Qty	Comment
6-pin header	U30	6-pin header	1	See orientation
1uF	C3	0805	1	
2.00K	R3, R5	0603	2	
1.5-SMT, 1%	R1	2010	1	
2-pin header	U19, U27, U28	2-pin header	3	See orientation
100	R2, R4	0603	2	
100nF	C4, C5	0805	2	
MAX4230	U1	SC70_5	1	
TempSensor	U2	SOT23	1	
ZXMN6A07F	U3	SOT23	1	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix E Rebel Driver Board (v 4.1) Bill of Materials for SOP A1-3 Driver Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix F
Rebel Driver Board (v 4.1) Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0		None

These instructions are to be included in the fabrication package for the Rebel Driver Board (v 4.1) when shipped to Nashua circuits for fabrication.

1. All files provided: Gerber files for top and bottom sides: Copper, Silkscreen, Paste mask, Board outline, Solder mask, Drill mask, Drill file.
2. Paste mask will be provided by the Frangioni Laboratory, stepped by Nashua Circuits, and sent to Sure Design.
3. Thickness of board: 2 layers, 0.062”
4. Key dimensions: Final board is circular 26.5 mm ± 0.005” (± 0.127 mm) in diameter, but will be manufactured in a pallet fashion to assist Sure Design with soldering.
5. Boards need to be clean from any contamination.
6. Pallets are checked (NRE) by Nashua Circuits.
7. Pallets are pre-cut by Nashua Circuits.
8. Metal “pour”: Standard 1 oz. (= 0.0014” = 0.036 mm) which ends up on the board as 2X = 2 oz. = 0.0028” = 0.072 mm.
9. Color of Mask: Green

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix F Rebel Driver Board (v 4.1) Fabrication Instructions for SOP A1-3 Driver Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix G
Rebel Driver Board (v 4.1) Assembly Instructions

Version 0 (10/01/2011)

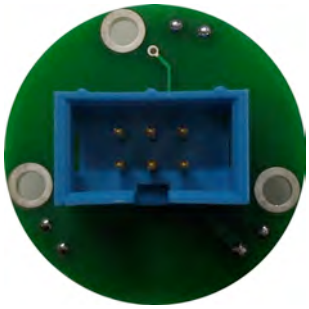
Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

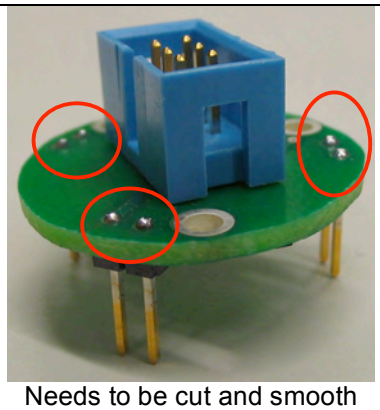
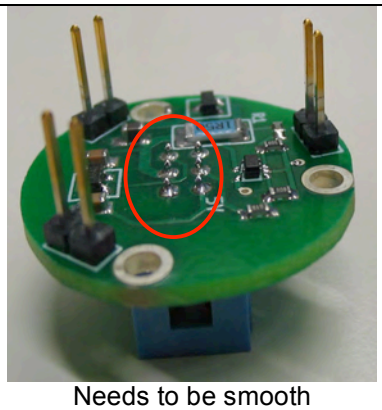
Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0		A1-3 Appendix E
		A1-3 Appendix F

These instructions are to be included in the fabrication package for the Rebel Driver Board (v 4.1) when shipped to Sure Design for assembly.

1. Driver boards need to be smooth and round without bumps.
2. ICs will be soldered using oven soldering.
3. Stepped mask is provided by Nashua Circuits to Sure Design; the stencil mask will be made from it.
4. Boards need to be clean from any contamination.
5. ICs are electrostatically very sensitive and need to be grounded for proper handling.
6. The top of the 2-pin headers needs to be cut.
7. All through-board soldering (2-pin and 6-pin headers) needs to be smooth to avoid sharp edges (see figures).
8. Assembly instructions are provided in these fabrication notes.
9. Boards will be tested after assembly.

Bottom	*Top*
	

Rebel Driver Board - Version 4.1

 Needs to be cut and smooth	 Needs to be smooth

Sharpness of Through-Hole Components

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix G Rebel Driver Board (v 4.1) Assembly Instructions for SOP A1-3 Driver Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-3 Appendix H
Rebel Driver Board (v 4.1) Layout

Version 0 (10/01/2011)

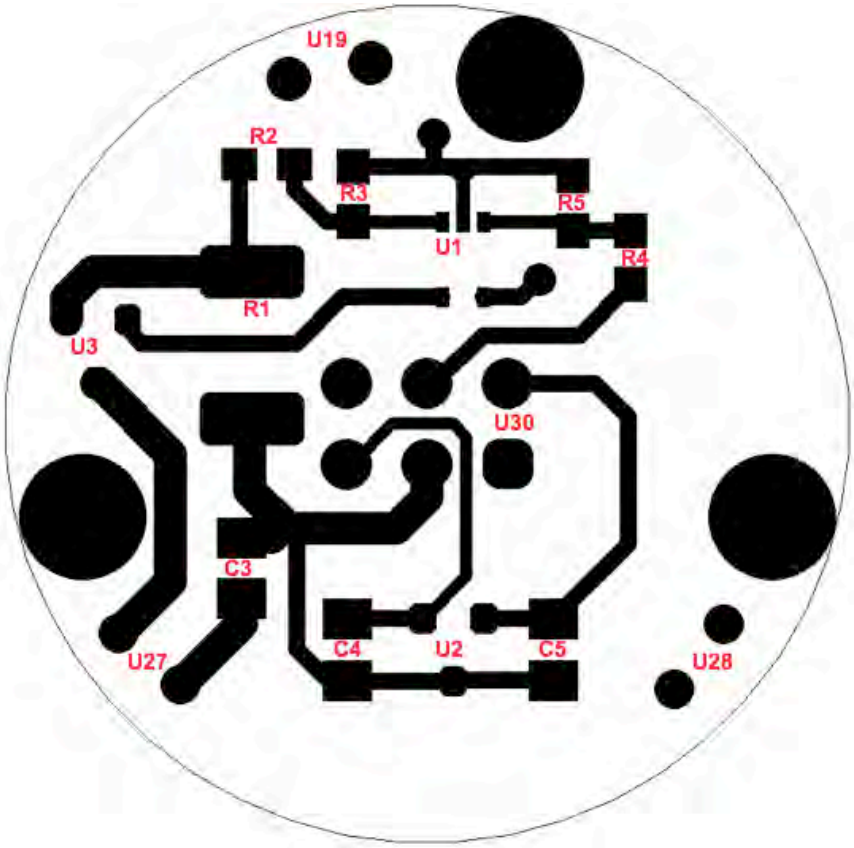
Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

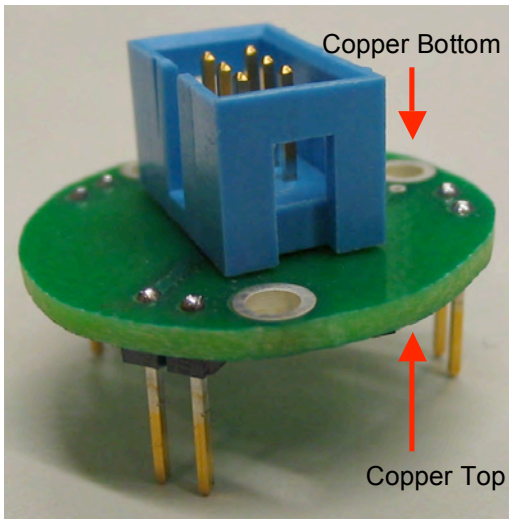
Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-3 Driver Board – v 2.0		A1-3 Appendix G

Rebel Driver Board (v 4.1) Layout

Top



Rebel Driver Board (v 4.1) Orientation



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-3 Appendix H Rebel Driver Board (v 4.1) Layout for SOP A1-3 Driver Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4
LED Board

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Authors: Barbara Clough Alan Stockdale	04/14/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	T1-5 Visual Inspection of LED Board 1	A1-4 Appendix A
	T1-6 Visual Inspection of LED Board 2	A1-4 Appendix B
	T2-3 Short Testing for LED Board	A1-4 Appendix C
	T7 Leak Testing	A1-4 Appendix D

		A1-4 Appendix E
		A1-5 Appendix F

1. PURPOSE

The purpose of this document is to outline the procedures for fabricating and assembling the LED board used with the FLARE™ (Fluorescence-Assisted Resection and Exploration) imaging system for the Frangioni Laboratory.

2. SCOPE

This procedure applies to all personnel assembling the boards for the FLARE™ imaging system.

3. POLICIES AND RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

The following forms must be completed and kept in the master device file.

F1 Appendix A Shipping and Receiving Form
T1-5 Appendix A LED Board 1 Testing Form
T1-6 Appendix A LED Board 2 Testing Form
T2-3 Appendix A LED Board Short Testing Form

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A1-4 Appendix A LED Board (v 1.2) Bill of Materials
A1-4 Appendix B LED Board (v 1.2) Fabrication Instructions
A1-4 Appendix C LED Board (v 1.2) Assembly Instructions
A1-4 Appendix D Rebel LED Board (v 2.0) Bill of Materials
A1-4 Appendix E Rebel LED Board (v 2.0) Fabrication Instructions
A1-4 Appendix F Rebel LED Board (v 2.0) Assembly Instructions

6. PROCEDURES

Steps	
A.. The approved design is created and a Gerber file is generated from this design. The approved design receives a specific revision number. A copy of the Gerber file is archived.	
B. The design is sent to Sure Design and Nashua Circuits for review.	
C. The approved design is sent to Nashua Circuits for fabrication. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
D. Nashua Circuits produces a board according to specifications and approved design. The board has a specific set of tests to be performed by Nashua Circuits before being shipped back to BIDMC.	
E. To receive the fabricated board, complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
F. Perform visual inspection and functional testing according to the board type and specified in SOP T1-5 Visual Inspection of LED Board 1. Form Required: Complete T1-5 Appendix A LED Board 1 Testing Form; this form is to be kept in the master device file.	
G. The inspected boards, their components, and SOP A1-4 Appendix A or A1-4 Appendix D depending on the LED board are sent to Sure Design for assembly. Board specific assembly instructions and board specific materials and components are also included. Form Required: Complete F1 Appendix A Shipping	

and Receiving form; this form is to be kept in the master device file.	
H. The assembled boards are visually inspected at Sure Design. The inspection is performed according to the instructions that have been included with the shipment of materials.	
I. The inspected assembled board and all unused components are shipped to BIDMC. To receive the fabricated Driver Board, complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the master device file.	
J. Upon receipt of the assembled board, visual and functional inspections are performed according to SOPs T1-6 Visual Inspection of LED Board 2, T2-3 Short Testing for LED Board, and T7 Leak Testing. Form Required: Complete T1-6 Appendix A LED Board 2 Testing Form, T2-3 LED Board Short Testing Form, and T7 Leak Testing Form; these forms are to be kept in the master device file.	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP LED board fabrication and assembly.	04/14/2009	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Edited.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4 Appendix A
LED Board (v 1.2) Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-4 LED Board		

This Bill of Materials is for the assembly of the LED Board (Version 1.2) at Sure Design.

Table 1. Bill of Materials for LED Board (Version 1.2)

Qty.	Description	Vendor	Part #
12 per board	NIR LEDs: 760 ± 4 nm LED, 5 mm, 18 mW @ 50 mA, ±10˚ half-angle	Epitex	L760-01AU
12 per board	RED LEDs: 670 ± 5 nm LED, 5 mm, 18 mW @ 50 mA, ±10˚ half-angle	Epitex	L670-01
2 per board	Connector: 2-pin through-board, pass-through header receptacle for LEDs	Samtec	BCS-102-L-S-DE

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-4 Appendix A LED Board (v 1.2) Bill of Materials for SOP A1-4 LED Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4 Appendix B
LED Board (v 1.2) Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-4 LED Board		None

These instructions are to be included in the fabrication package for the LED Board (v 1.2) when shipped to Nashua Circuits for fabrication.

1. Gerber files are provided

> **Note:** Ken Thomas from Sure Design has modified these Gerbers from our original Ultiboard software to eliminate perforation marks around each hole. Ultiboard cannot otherwise have a smooth transition between the main metallization of PCB and metal rings around each hole.

2. Thickness of board: 0.062: (standard size)

3. Key dimensions: Final LED boards are round with a diameter of 26.5 mm and a tolerance of ±0.005" (± 0.127 mm).

4. Metal "pour": These LED boards should be poured with 2 oz., which should end up being 3 oz. = 0.0042" = 0.107 mm (on each side of the board, so 0.214 mm total for a double-sided board). This extra thickness of metal helps with thermal transfer. Nashua Circuits needs to make sure all tracings will work with this pour.

5. Mask: This is a special purpose PCB that has MINIMAL solder mask. The ONLY solder mask appears as thin rings around the LED holes. The color of this mask should be RED. Otherwise, this board should have BARE METAL on most of the exposed surfaces.

6. LED boards should be produced panelized and sent to BIDMC for inspection. After inspection, hey will be sent to Sure Design in panels for assembly. Sure Design will be responsible for cutting them out and sanding edges.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-4 Appendix B LED Board (v 1.2) Fabrication Instructions for SOP A1-4 LED Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4 Appendix C
LED Board (v 1.2) Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-4 LED Board		A1-4 Appendix A
		A1-4 Appendix B

These instructions are to be included in the assembly package for the LED Board (v 1.2) when shipped to Sure Design for assembly.

1. LED boards need to be smooth and round without bumps.
2. LEDs will be assembled perfectly perpendicular to the surface of the board.
3. Boards need to be clean from any contamination.
4. All through board soldering needs to be smooth to avoid sharp edges.
5. Assembly instructions are provided by BIDMC in these fabrication notes.
6. Board will be visually inspected after assembly. Special attention should be paid to the above-mentioned features.
7. Special attention should be paid to protecting the boards during shipment.

Figure 1. LED board assembly (Version 1.2)

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-4 Appendix C LED Board (v 1.2) Assembly Instructions for SOP A1-4 LED Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4 Appendix D
Rebel LED Board (v 2.0) Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-4 LED Board		

This Bill of Materials is for the assembly of the Rebel LED Board (Version 2.0) at Sure Design.

Table 1. Bill of Materials for Rebel LED Board (Version 2.0)

Qty.	Description	Vendor	Part #
1	Luxeon Rebel, cool white LED	Philips - LumiLEDs	LXML-PWC1-0100
2 per board	Connector: 2-pin through-board, pass-through header receptacle for LEDs	Samtec	BCS-102-L-S-DE

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-4 Appendix D Rebel LED Board (v 2.0) Bill of Materials for SOP A1-4 LED Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4 Appendix E
Rebel LED Board (v 2.0) Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-4 LED Board		None

These instructions are to be included in the fabrication package for the Rebel LED Board (v 2.0) when shipped to Nashua Circuits for fabrication.

1. Gerber files are provided.

2. Thickness of board: 0.062” (standard size).

3. Key dimensions: Final LED boards are round with a diameter of 26.5 mm and a tolerance of ±0.005” (± 0.127 mm).

4. Metal “pour”: Starting copper weight is 2 oz., plated up to 3 oz. (on each side of the board, so 0.214 mm total for a double-sided board). This extra thickness of metal helps with thermal transfer. Nashua Circuits needs to make sure all tracings will work with this pour.

5. Mask: This is a special purpose PCB that has MINIMAL solder mark. Both solder mask files represent positive imaging. For the top-side mask (*luxeon_v2_0(rebel) - solder mask top-NEW.gbr)* there are four rings around four plated through holes 0.036 and a solder mask dam around a land pattern (RND 0.008). On the bottom side mask (*luxeon_v2_0(rebel) - solder mask bottom-mod.gbr)* the same four rings occupy the same four plated 0.036 holes. These are the only mask features that exist on this PCB. All other areas to be free of mask as indicated in the files.

6. LED boards should be produced panelized and sent back to BIDMC for inspection. After inspection, they will be sent to Sure Design in panels for assembly. Sure Design will be responsible for cutting them out and sanding edges.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-4 Appendix E Rebel LED Board (v 2.0) Fabrication Instructions for SOP A1-4 LED Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-4 Appendix F
Rebel LED Board (v 2.0) Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-4 LED Board		A1-4 Appendix D
		A1-4 Appendix E

These instructions are to be included in the assembly package for the Rebel LED Board (v 2.0) when shipped to Sure Design for assembly.

1. LED boards need to be smooth and round without bumps.
2. LEDs will be as shown below, ensuring proper orientation of LED on SMT pads.
3. Boards need to be clean from any contamination.
4. All through board soldering needs to be smooth to avoid sharp edges.
5. Assembly instructions are provided by BIDMC in these fabrication notes.
6. Boards will be visually inspected after assembly. Special attention should be paid to the above-mentioned features.
7. Special attention should be paid to protecting the boards during shipment.

Figure 1. Rebel LED Board Assembly (Version 2.0)

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-4 Appendix F Rebel LED Board (v 2.0) Assembly Instructions for SOP A1-4 LED Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-5
Temperature Sensor

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Authors: Barbara Clough Alan Stockdale	04/14/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	None	A1-5 Appendix A
		A1-5 Appendix B
		A1-5 Appendix C

1. PURPOSE

The purpose of this document is to outline the procedures for fabricating and assembling the temperature sensor used with the FLARE™ (Fluorescence-Assisted Resection and Exploration) imaging system for the Frangioni Laboratory.

2. SCOPE

This procedure applies to all personnel assembling the temperature sensors for the FLARE™ imaging system.

3. POLICIES AND RESPONSIBILITIES

It is the responsibility of the Principal Investigator to assure adherence to protocols. These tasks are to be performed by personnel designated by the Principal Investigator.

4. FORMS

The following forms must be completed and kept in the master device file.

F1 Appendix A Shipping and Receiving Form

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A1-5 Appendix A Bill of Materials
A1-5 Appendix B Fabrication Instructions
A1-5 Appendix C Assembly Instructions

6. PROCEDURES

Steps	
A.. The approved design is created and a Gerber file is generated from this design. The approved design receives a specific revision number. A copy of the Gerber file is archived.	
B. The approved design is sent to Nashua Circuits for fabrication. Nashua Circuits produces a board according to specifications and approved design. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
C. To receive the fabricated Temperature Sensor,	

complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
D. The fabricated boards are visually inspected to check for proper orientation of components to ensure that no breaks or shorts are present in the assembly.	
E. The inspected boards and their components are assembled in house with materials presented in SOP A1-5 Appendix A..	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for A1-5 Temperature Sensor.	04/14/2009	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Edited.	06/1/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/1/2011	Lorissa Moffitt David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-5 Appendix A
Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-5 Temperature Sensor		

This Bill of Materials is for the in-house assembly of the Temperature Sensor.

Table 1. Bill of Materials 1

Qty.	Description	Vendor	Part #
2	Vishay 0.1uF capacitors, 0805 form factor	Mouser	77-VJ08Y50V104K
1	National Semiconductor LM50 Tempurature Sensor	Digikey	LM50CIM3CT-ND
1	3-pin surface mount header	Samtec	TSM-103-01-L-SH

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-5 Appendix A Bill of Materials for SOP A1-5 Temperature Sensor	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-5 Appendix B
Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	4/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-5 Temperature Sensor	None	None

These instructions are to be included in the fabrication package for the Temperature Sensor when shipped to Nashua Circuits for fabrication.

1. All files provided: Gerber files for top and bottom sides: Copper, Silkscreen, Paste mask, Board outline, Solder mask, Drill mask, Drill file.

2. Thickness of board: 2 layers, 0.062".

3. Key dimensions: Final board is square, 17 mm by 1.7 mm, but will be manufactured in a pallet fashion to assist Sure Design with soldering.

4. Boards need to be clean from any contamination.

5. Pallets are checked (NRE) by Nashua Circuits.

6. Pallets are pre-cut by Nashua Circuits.

7. Metal "pour": Standard 1 oz. (= 0.0014" = 0.036 mm), which ends up on the board as 2X = 2 oz. = 0.028" = 0.072 mm).

8. Color of Mask: Black

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-5 Appendix B Fabrication Instructions for SOP A1-5 Temperature Sensor	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-5 Appendix C
Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-5 Temperature Sensor		A1-5 Appendix A
		A1-5 Appendix B

These instructions are to be included in the assembly package for the Temperature Sensor for In house assembly.

1. Temperature sensor boards need to be smooth and without bumps.
2. All components will be hand-soldered in-house.
3. Boards need to be clean from any contamination.
4. ICs are electro-statically very sensitive. The assembler needs to be grounded.

View of Board after Assembly

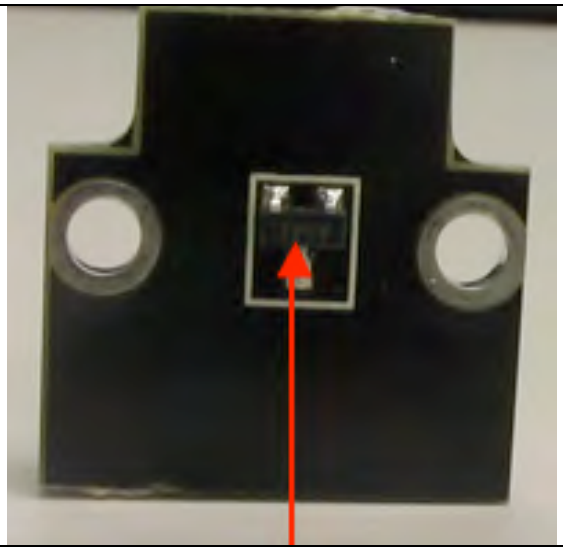


Figure 1. Bottom view of assembly. Arrow indicates the temperature sensor

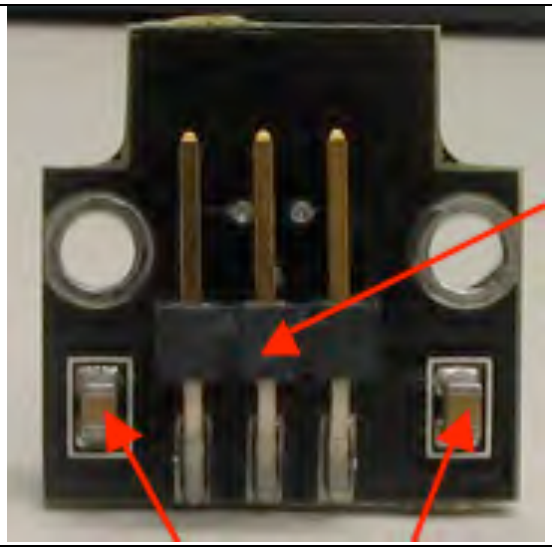


Figure 2. Top view of assembly. Top arrow indicates 3-pin header. Bottom arrows (2) indicate 0.1 uF capacitors.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-5 Appendix C Assembly Instructions for SOP A1-5 Temperature Sensor	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-6
Footswitch Board

Version 2.0 (11/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Authors: Barbara Clough Alan Stockdale	04/22/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None.	A1-6 Appendix A
		A1-6 Appendix B
		A1-6 Appendix C
		A1-6 Appendix D

1. PURPOSE

The purpose of this document is to outline the procedures for fabricating and assembling the Footswitch Board used with the FLARE™ (Fluorescence-Assisted Resection and Exploration) imaging system for the Frangioni Laboratory.

2. SCOPE

This procedure applies to all personnel assembling the Footswitch Board for the FLARE™ imaging system.

3. POLICIES AND RESPONSIBILITIES

It is the responsibility of the Principal Investigator to assure adherence to protocols. These tasks are to be performed by personnel designated by the Principal Investigator.

4. FORMS

The following forms must be completed and kept in the master device file.

F1 Appendix A Shipping and Receiving Form

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A1-6 Appendix A Bill of Materials
A1-6 Appendix B Fabrication Instructions
A1-6 Appendix C Assembly Instructions
A1-6 Appendix D Layout

6. PROCEDURES

Steps	
A. The approved design is created and a Gerber file is generated from this design. The approved design receives a specific revision number. A copy of the Gerber file is archived.	
B. The approved design is sent to PCB Express/Sunstone for fabrication. PCB Express/Sunstone produces a board according to specifications and approved design. Form Required: Complete F1 Appendix A	

Shipping and Receiving form; this form is to be kept in the master device file.	
C. To receive the fabricated Temperature Sensor, complete F1 Appendix A Shipping and Receiving Form; this form is to be kept in the manufacturing records for the individual device. Attach receipt paperwork to form. Form Required: Complete F1 Appendix A Shipping and Receiving form; this form is to be kept in the master device file.	
D. The fabricated boards are visually inspected to check for proper orientation of components to ensure that no breaks or shorts are present in the assembly.	
E. The inspected boards and their components, found in SOP A1-6 Appendix A, are assembled and inspected in house.	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Create new SOP for Footswitch board.	4/22/2009	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Edited.	6/1/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/1/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-6 Appendix A
Bill of Materials

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-6 Footswitch Board		

This Bill of Materials is for the in-house assembly of the Footswitch Board.

Table 1. Bill of Materials

Value	Shape	Qty	RefDes	Mfg.	Part #	Distributor	Part #
1uF	Thru-hole	6	C1, C2, C3, C4, C5, C6	Kemet	T350A105K 035AT	Digikey	399-3529-ND
4.7k, 1/4W	Thru-hole	6	R7, R8, R9, R10, R11, R12	Yageo	CFR-25JB-4K7	Digikey	4.7KQBK-ND
Zero Ohm jumper, 1/4W shape	Thru-hole	6	R13, R14, R15, R16, R17, R18	Yageo	ZOR-25-B-52	Digikey	0.0QBK-ND
100, 1/2W	Thru-hole	6	R1, R2, R3, R4, R5, R6	Yageo	CFR-50JB-100R	Digikey	100H-ND
CD40106B	DIP14	1	U1	Texas Instrument	CD40106BE	Digikey	296-3503-5-ND
HDR1X7	7-pin screw terminal	1	J2	On Shore Tech	OSTTC070162	Digikey	ED2605-ND
HDR1X8	8-pin screw terminal	1	J1	On Shore Tech	OSTTC080162	Digikey	ED2606-ND

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-6 Appendix A Bill of Materials for SOP A1-6 Footswitch Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-6 Appendix B
Fabrication Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-6 Footswitch Board		None

These instructions are to be included in the fabrication package for the Footswitch Board when shipped to PCB Express/Sunstone Circuits.

1. All files provided: Gerber files for top and bottom sides. Copper, Silkscreen, Paste mask, Board outline, Solder mask, Drill mask, Drill file.

2. Thickness of board: 2 layers, 0.062”.

3. Key dimensions: Final board is rectangular, 3.5” by 4.7”.

4. Boards need to be clean from any contamination.

5. Metal “pour”: Standard 1 oz. (= 0.0014” = 0.036 mm) which ends up on the board as 2X = 2 oz. = 0.0028” = 0.072 mm.

6. Color of Mask: Green

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-6 Appendix B Fabrication Instructions for SOP A1-6 Footswitch Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-6 Appendix C
Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-6 Footswitch Board	None	A1-6 Appendix A
		A1-6 Appendix B
		A1-6 Appendix D

These instructions are to be included in the assembly package for the Footswitch Board when shipped to In house.

1. Footswitch boards need to be smooth and without bumps.
2. All components will be hand soldered.
3. Boards need to be clean from any contamination.
4. ICs are electro-statically very sensitive – the assembler needs to be grounded.
5. All through board soldering needs to be smooth to avoid sharp edges.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-6 Appendix C Assembly Instructions for SOP A1-6 Footswitch Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A1-6 Appendix D Layout

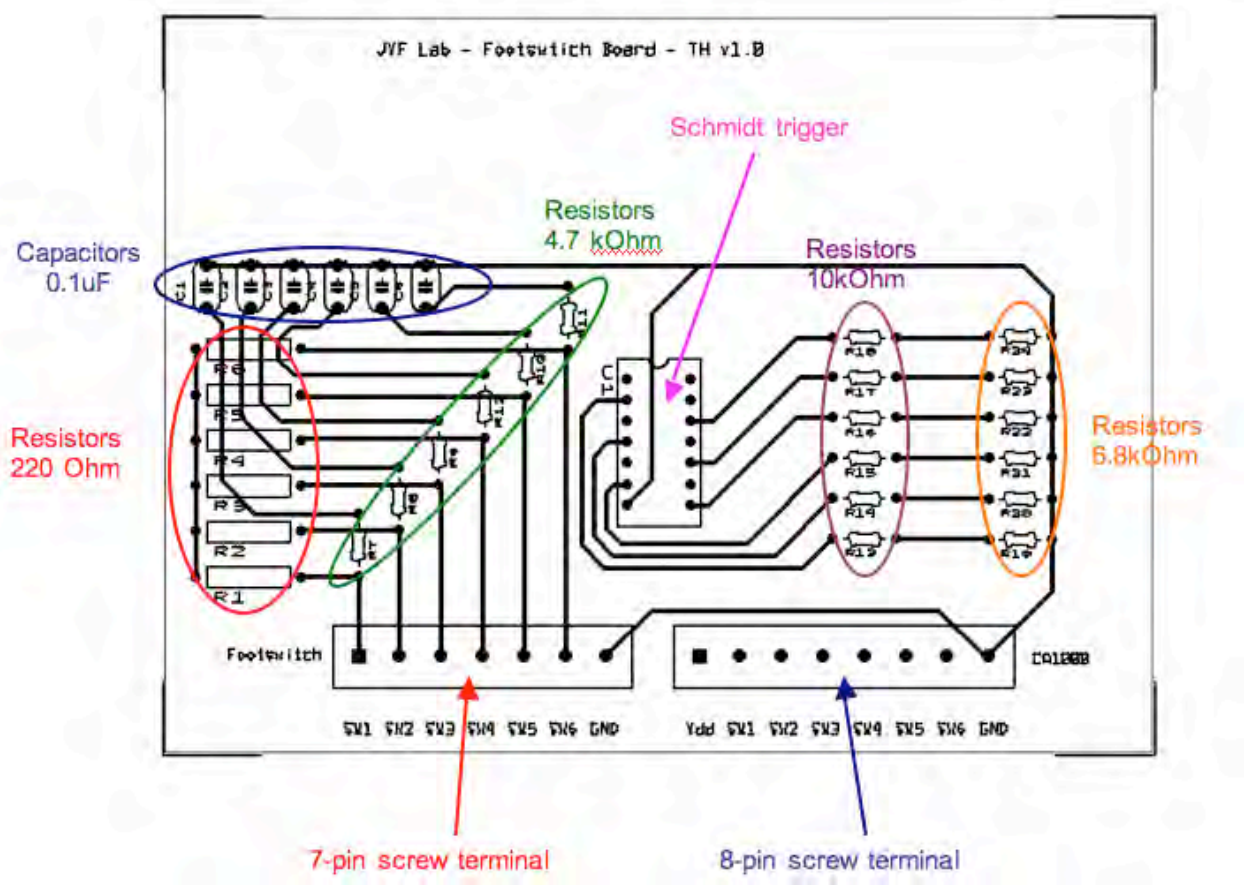
Version 0 (10/01/2011)

Approval Signatures

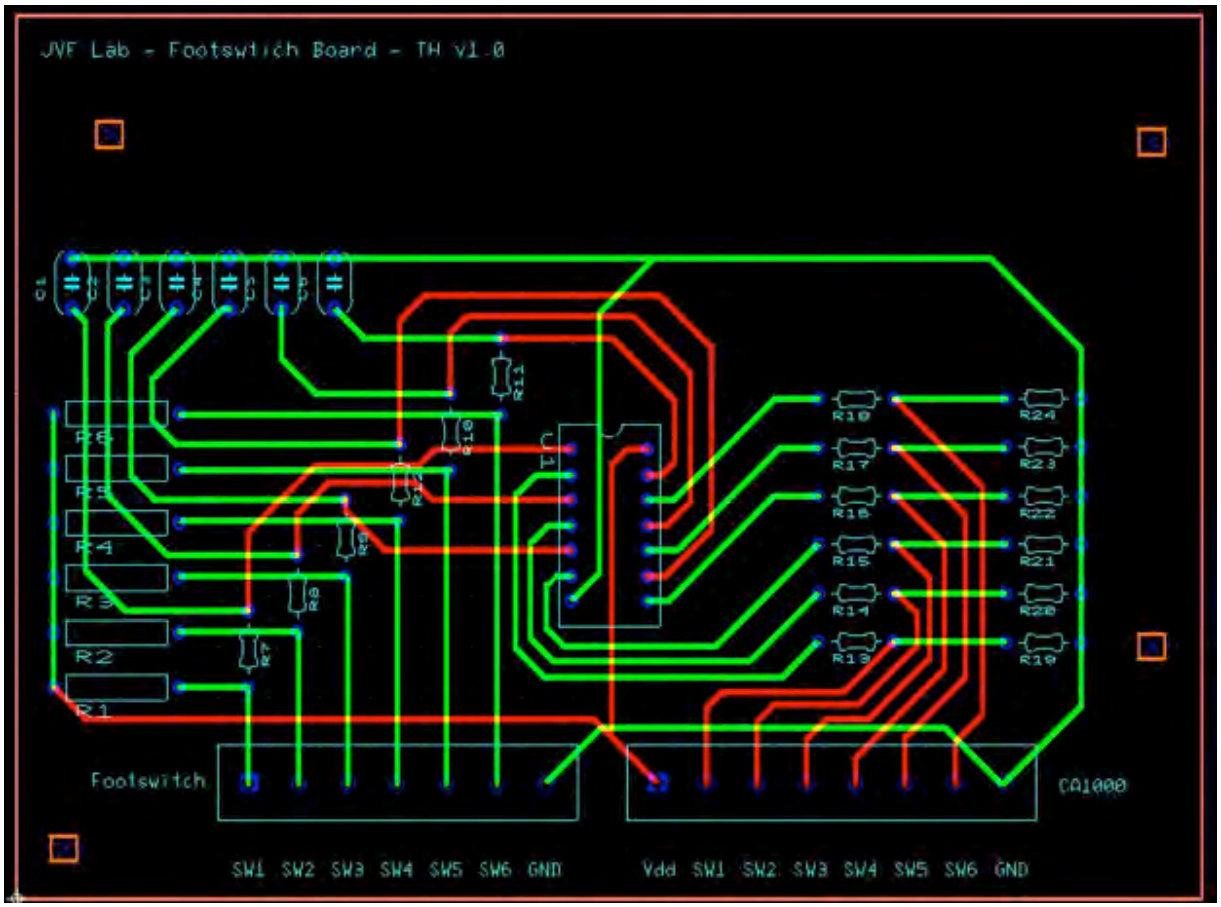
Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-6 Footswitch Board		A1-6 Appendix C

Footswitch Board Component Layout



View of Footswitch Board



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A1-6 Appendix D Layout for SOP A1-6 Footswitch Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A-2
Active Board Embedded Code Software

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Authors: Barbara Clough Alan Stockdale	05/08/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	None.	A2 Appendix A

1. PURPOSE

The purpose of this document is to outline the procedures for embedding the Active Board Software used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel embedding the Active Board Software for assembly of the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

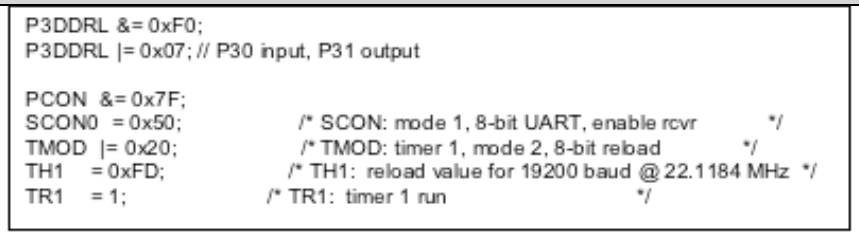
There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A2 Appendix A Specifications
A1-1 Active Board

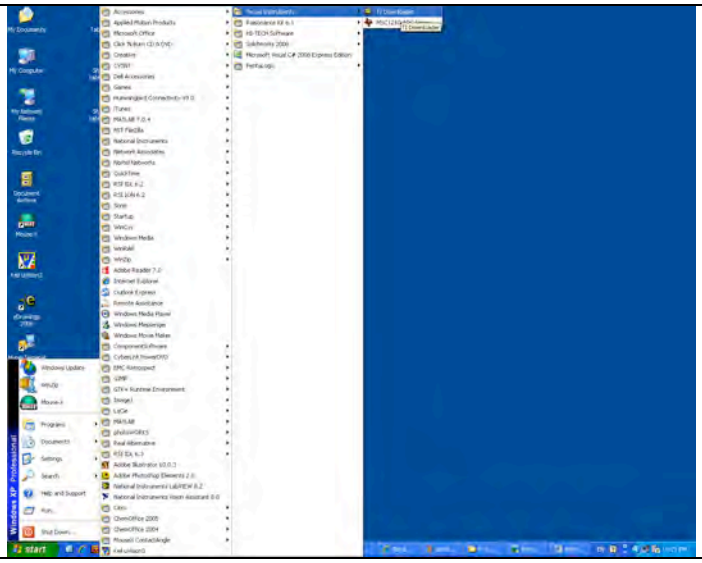
6. PROCEDURES

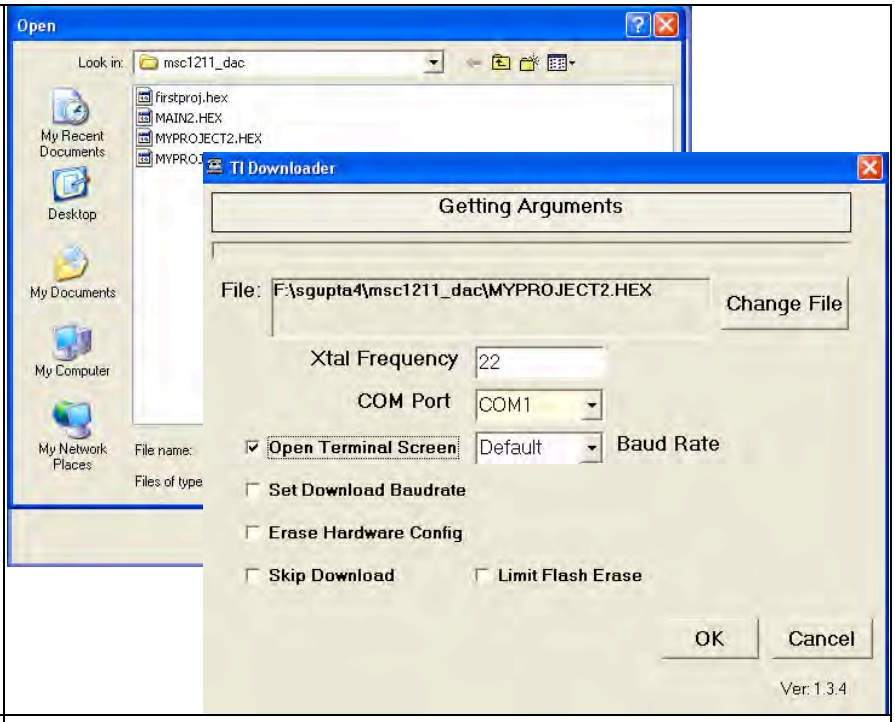
Step 1. Initialization	
A. Initialize the serial communication with the PC. This is accomplished by setting the correct pins of Port 3 to be inputs and outputs, and set the timer that controls the clock.	

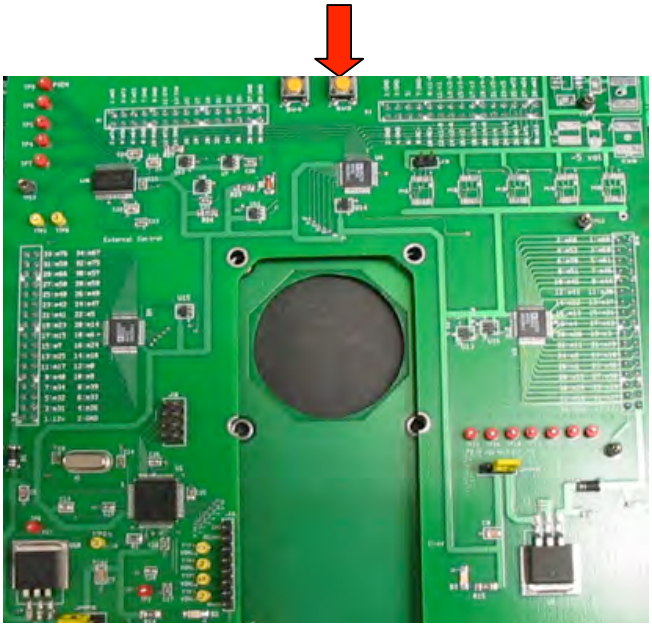
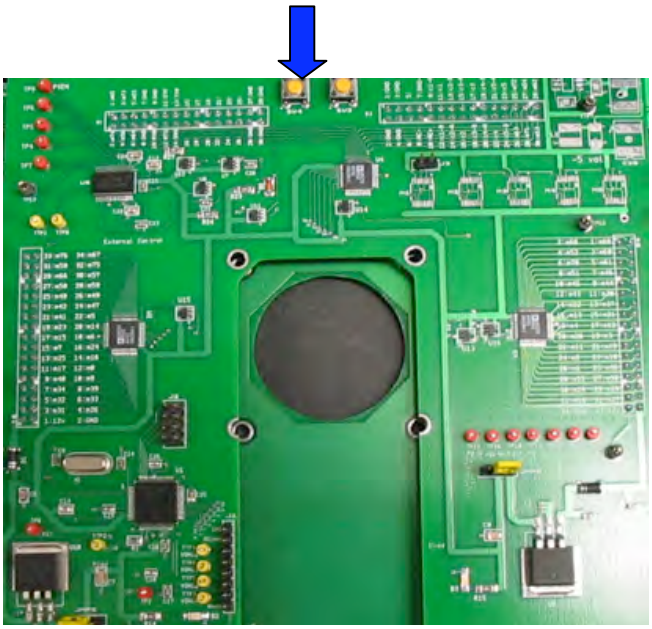
B. The SPI should be set, as this will control all five control lines.	P3DDRL &= 0xF0; P3DDRL |= 0x07; // P30 input, P31 output PCON &= 0x7F; SCON0 = 0x50; /* SCON: mode 1, 8-bit UART, enable rcvr */ TMOD |= 0x20; /* TMOD: timer 1, mode 2, 8-bit reload */ TH1 = 0xFD; /* TH1: reload value for 19200 baud @ 22.1184 MHz */ TR1 = 1; /* TR1: timer 1 run */

C. The serial interrupt needs to be initialized; this is how commands are received from the PC.	ES = 1;
	REN_0 = 1;
	//TR0 = 1; /* TR0: Timer 0 run */
	EA = 1; /* EA: Enable interrupts */

Step 2. Infinite Loop	
D. After initializing the microcontroller, the infinite loop will start when the "while(1)" loop starts. Inside the loop, the program will continuously monitor Port 2 of the microcontroller. This port monitors pins 0 to 6 which are lines from the multiplexers, which in turn monitor the temperature readings.	
E. With a small delay, the program will take in a value from AIN0, send it to the PC, increment Port 2, and then read the next value available to AIN0. This will repeat throughout the loop.	
Step 3. Serial Interrupt	
F. The serial interrupt is called whenever the PC sends a command, which happens only when one of the five light sources needs to change intensity. The microcontroller will receive two bytes; the first will determine which light to control while the second will determine at what intensity is to be	

set.	
G. When the first byte comes in, it will be saved in a different variable name before it is overwritten by the second byte coming in. Once both are in, a first byte will be sent to the off-chip DAC. This will represent which of the five DACs is to be used. The second byte will be a representation of the intensity to send to the light source. This will come in to the microcontroller as a percentage (0-100%), which will be converted into the 0-51 range (since the maximum of the control lines is 1 V, which corresponds to 51 on the DAC). This second byte is then sent to the DAC as well.	
H. The software to be loaded will be a .HEX file. It is loaded in the following manner.	
I. Go to Programs -> Texas Instruments -> TI Downloader	

J. The following windows will open. (NB: These are examples only; the location of the file and the version of the code that will be loaded may change.) Choose the name "FINAL_PROJECT.HEX" and click "Open."	
K. Ensure that the Xtal Frequency is 22, that COM 6 is chosen, and check the box that reads "Open Terminal Screen." Click "OK." The program will download to the microcontroller and an empty terminal screen will be opened. The program has been loaded onto the microcontroller.	

L. Pressing the RESET button (pointed to by the arrow) resets the software. The RESET button forces the uController to program if the RS232 signals fail to do so (similar to the RST button that forces the program to start if the RS232 signals fail). By pressing the button down, 0 volt is applied to PSEN input of the uController, which brings the uController state to Serial Programming mode. During normal operation the button should never be pressed.	
M. The PRG LD button (left of the RESET button) is only used twice per system: 1) for loading the test program, and 2) for loading the final program.	

Note: TI downloader is sending the proper reset signal to start the embedded code. In everyday application the TI downloader will not be used. The reset is implemented in the GUI software.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Active Board Embedded Code Software.	05/08/2008	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Reformatted.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Edited and reformatted.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A2 Appendix A Specifications

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A2 Active Board Embedded Code Software		

Specifications for Active Board Embedded Code Software

Where is the PC?

The embedded code downloaded to the microcontroller will be initially written in C, and then converted to HEX by the IDE. It will serve two main functions:

1. To receive commands from the PC that will change the intensity of the light sources.
2. To monitor the temperature sensors in the light modules and send the information back to the PC.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A2 Appendix A Specifications for SOP A1-6 Footswitch Board	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A3
LED, Jumper, and Filter Maps

Version 2.1 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Authors: Barbara Clough Alan Stockdale	05/08/2008		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	None.	A3 Appendix A
		A3 Appendix B
		A3 Appendix C
		A3 Appendix D

1. PURPOSE

The purpose of this document is to outline the procedures mapping the LEDs, Jumpers, and Filters used with the Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel mapping the LEDs, Jumpers, and Filters for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

A. FORMS

There are no forms for this SOP.

B. MATERIALS AND EQUIPMENT

The following materials will be needed for the completion of this SOP.

Clinical System Only
SOP A3 Appendix A Materials for Clinical Use Systems
SOP A3 Appendix B Mapping for Clinical Use
Research System Only
SOP A3 Appendix C Materials for Research Use Systems
SOP A3 Appendix D Mapping for Research Use

6. PROCEDURES

LED Mapping
Refer to Appendix B or D for placement/mapping of LED modules for Clinical and Research Systems, respectively.
Jumper Mapping
A. The Passive and Active Boards control seventy-six (76) LED Modules in the housing. To ensure that the correct a) control voltage and b) forward voltage are applied to each module of a different color (as defined by Appendix B or Appendix D), the jumpers need to be set properly on the Passive Board.
B. Two sets of jumpers are set for each module. Refer to Appendix B or Appendix D for proper jumper mapping depending on Clinical or Research use.

C. On each header, the module number shown corresponds with the "m#" on the silk screen of the Passive Board. Use the LED Map of Appendix B or Appendix D to determine the color corresponding to each module on the Passive Board.

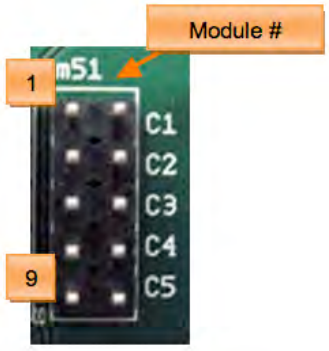


Figure 1. Silk Screen with "m#"

Filter Mapping

A. Use either Appendix B or Appendix D to select the necessary filters. Follow the module number and color-coding carefully.

B. Screw the filters in the proper LED location. Tooling may be required for corner modules are there is limited access. Screw the filters all the way in, especially in the corners to the shield can slide in easily.

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Jumper, Filter, LED maps.	05/08/2008	Barbara Clough Alan Stockdale
V 1.0	Modified Record	Edited.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/01/2011	Lorissa Moffitt
V 2.1	Modified Record	Edited	05/23/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A3 Appendix A
Materials and Equipment for Clinical Use Systems

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/23/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A3 LED, Jumper, and Filter Maps	None	None

The following materials are needed for the clinical use systems.

Item	Qty
NIR LEDs	36
Red LEDs	24
White LEDs	16
NIR/760 nm LED excitation filters (HMS3000-Ex762/34)	36
Red/670 nm LED excitation filters (HMS3000-Ex667/22)	24
White light LED excitation filter (HMS3000-Ex650SP)	16
Jumpers	152
Housing	1

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A3 Appendix A for SOP A3 Jumper, Filter, LED Maps	04/23/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A3 Appendix B
Mapping for Clinical Use

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/18/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A3 LED, Jumper, and Filter Maps		A3 Appendix A

A. LED Mapping for Clinical Use

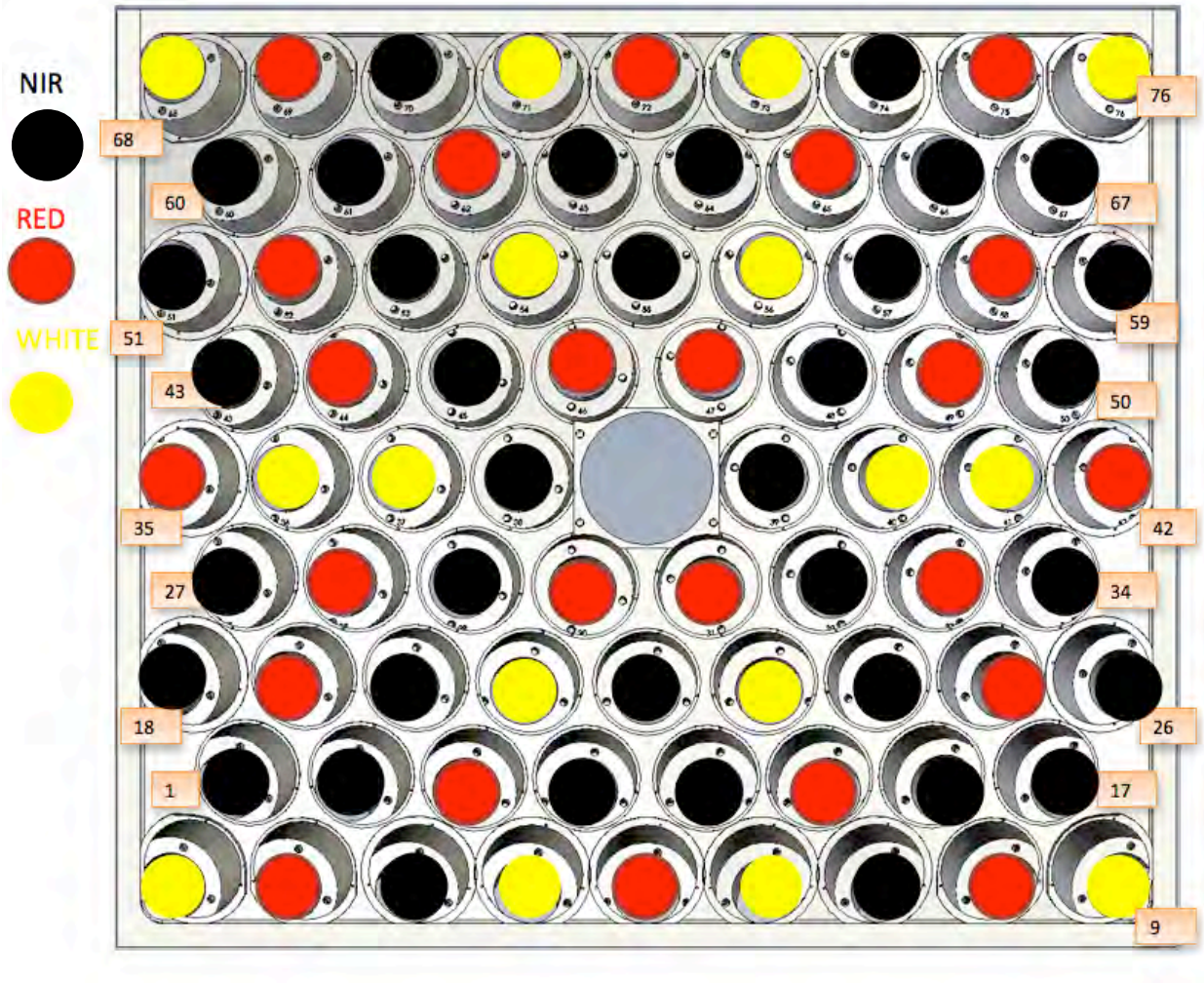


Figure 1. LED Map for Clinical Use.

B. Jumper Mapping for Clinical Use

The passive and active boards control seventy-six LED modules in the housing. To ensure that the correct a) control voltage and, b) forward voltage, is applied to each module of a different color (NIR, Red, and White) the jumpers need to be set properly on the passive board.

Two sets of jumpers are set for each module on the following headers: 1 x 3 header (12v, common), and 2 x 5 header: (c1, c2, c5).

1. On each header, the module number shown corresponds with "m#" on the silk screen (Figure 2) of the passive board. Use the LED Map for Clinical Use (Figure 1) to determine the color corresponding to each module on the passive board.

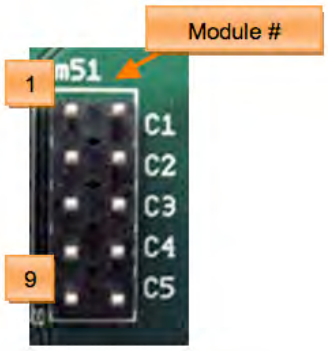


Figure 2. Silk Screen with "m#".

a. For 1 x 3 header setting, use the following placement of jumpers.

LED Color	Placement
NIR	Place a jumper between pin 1 (12v) and pin 2 (common)
Red	
White	

b. For 2 x 5 header setting, use the following placement of jumpers.

LED Color	Placement
NIR	Place a jumper on pins 1 and 2.
Red	Place a jumper on pins 3 and 4.
White	Place a jumper on pins 9 and 10.

C. Filter Mapping for Clinical Use

1. Use the LED Map for Clinical Use (Figure 1); follow the module # and color-coding carefully to select a correct filter for the corresponding color as given above.

2. Screw the filters in the proper LED location. Tooling may be required for corner modules as there is limited access. Screw the filters all the way in, especially in the corners so the shield can slide in easily.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A3 Appendix B Specifications for SOP A3 Jumper, Filter, LED Maps	04/18/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A3 Appendix C
Materials and Equipment for Research Use Systems

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/23/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A3 LED, Jumper, and Filter Maps	None	None

The following materials are needed for the research use systems.

Item	Qty
NIR LEDs	30
Red LEDs	24
White LEDs	10
Green LEDs	6
Blue LEDs	6
NIR/760 nm LED excitation filters (HMS3000-Ex762/34)	30
Red/670 nm LED excitation filters (HMS3000-Ex667/22)	24
White light LED excitation filter (HMS3000-Ex650SP)	10
Blue light LED excitation filter (HMS3000-Ex470/40)	6
Green light LED excitation filter (HMS3000-Ex525/50)	6
Jumpers	152
Housing	1

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A3 Appendix B for SOP A3 Jumper, Filter, LED Maps	04/23/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A3 Appendix D
Mapping for Research Use

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/1/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A3 LED, Jumper, and Filter Maps	None	A3 Appendix C

A. LED Mapping for Research Use

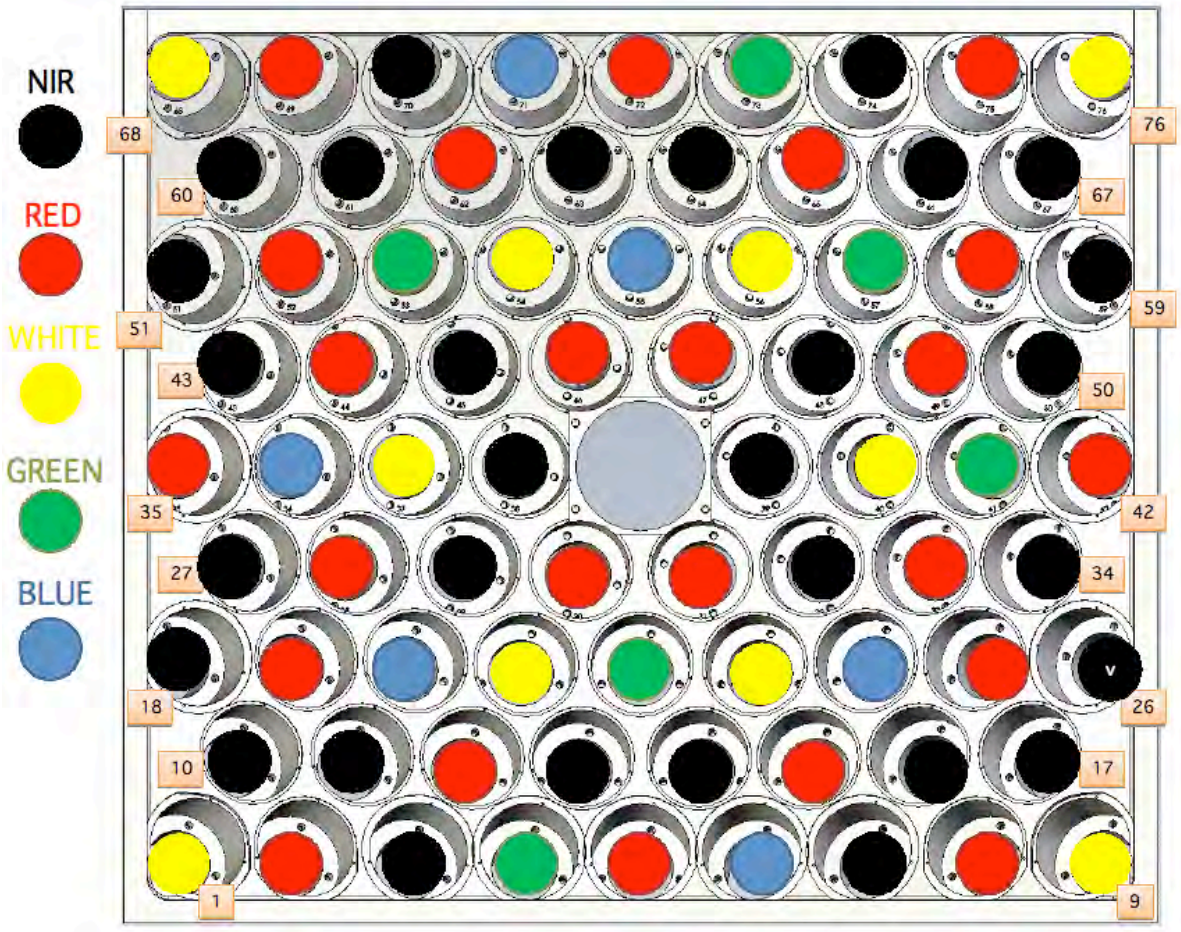


Figure 1. LED Map for Research Use

B. Jumper Mapping for Research Use

The passive and active boards control seventy-six LED modules in the housing. To ensure that the correct a) control voltage and, b) forward voltage, is applied to each module of a different color (NIR, Red, Green, Blue and White) the jumpers need to be set properly on the passive board.

Two sets of jumpers are set for each module on the following headers: 1 x 3 header (12v, common, 24v), and 2 x 5 header (c1, c2, c3, c4, c5).

1. On each header, the module number shown corresponds with "m#" on the silk screen (Figure 2) of the passive board. Use the LED Map for Research Use (Figure 1) to determine the color corresponding to each module on the passive board.

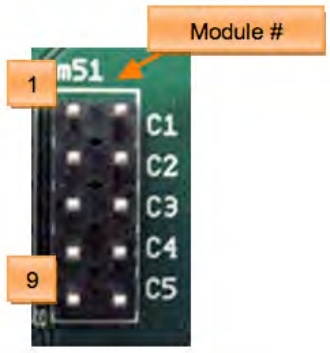


Figure 2. Silk Screen with "m#".

a. For 1 x 3 header setting, use the following placement of jumpers.

LED Color	Placement
NIR	Place a jumper between pin 1 (12v) and pin 2 (common)
Red	
White	Place a jumper between pin 3 (24v) and pin 2 (common).
Blue	
Green	

b. For 2 x 5 header setting, use the following placement of jumpers.

LED Color	Placement
NIR	Place a jumper on pins 1 and 2.
Red	Place a jumper on pins 3 and 4.
White	Place a jumper on pins 9 and 10.
Blue	Place a jumper on pins 7 and 8.
Green	Place a jumper on pins 5 and 6.

C. Filter Mapping for Research Use

1. Use the LED Map for Research Use (Figure 1); follow the module # and color-coding carefully to select a correct filter for the corresponding color as given above.

2. Screw the filters in the proper LED location. Tooling may be required for corner modules as there is limited access. Screw the filters all the way in, especially in the corners so the shield can slide in easily.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A3 Appendix D Mapping for Research Use for SOP A3 LED, Jumper, Filter Mapping.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A4
Active/Passive Board Assembly

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough	06/26/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-1 Active Board	None	None
A1-2 Passive Board		

1. **Purpose:** The purpose of this document is to outline the procedures for assembling the active and passive boards into one functional unit, which is used in the assembly of the clinical use FLARE™ (Fluorescence-Assisted Resection and Exploration) imaging system for the Frangioni Laboratory.

2. **Scope:** This procedure applies to all personnel assembling the boards for the FLARE imaging system.

3. **Responsibilities:** It is the responsibility of the Principal Investigator to assure adherence to protocols.

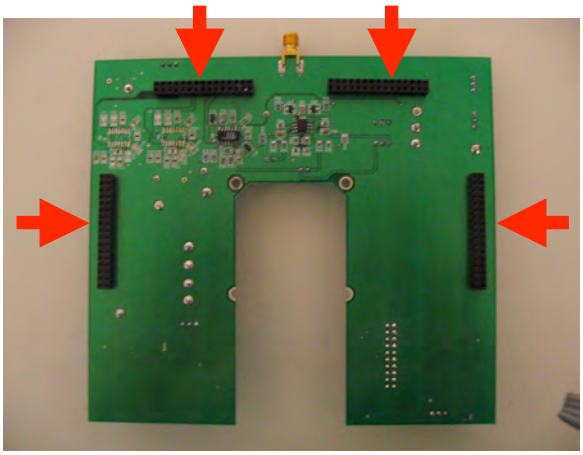
4. **Forms:** There are no forms for this SOP.

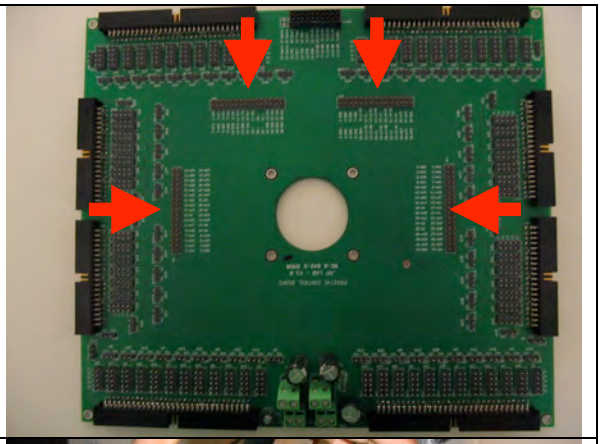
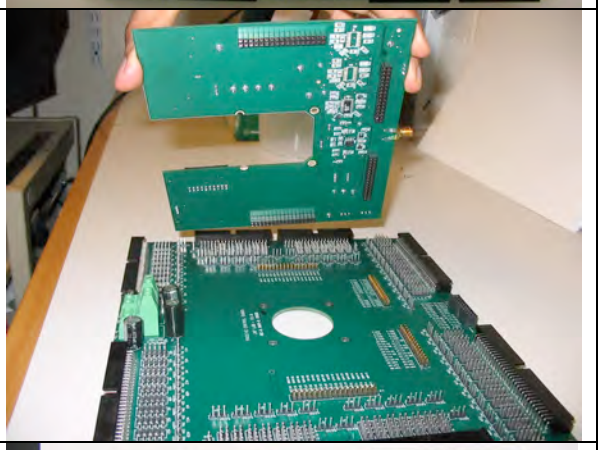
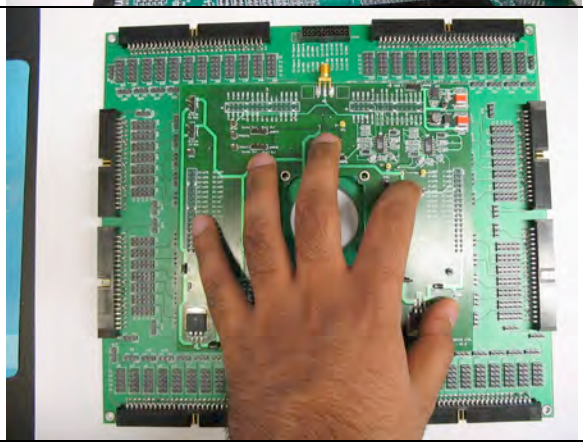
5. **Materials and Equipment:**

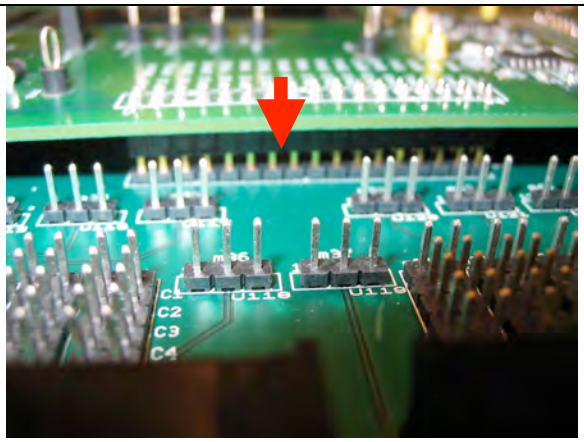
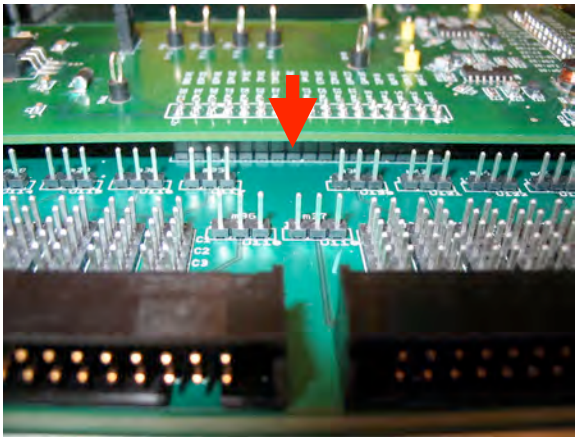
   The following materials will be needed for completion of this SOP.

A1-1 Active Board v 2.0
A1-2 Passive Board v 2.0

6. **Procedure:**

Steps	
A. The back of the Active Board contains four connectors, as does the front of the Passive Board. These connectors are pointed out by the arrows in the two figures to the right.	

	
B. Place the Passive Board on a flat surface, line up the four connectors and place the active board on top of the passive board.	
C. Making sure the connectors are properly aligned, push the Active Board until the connectors are well attached. NOTE: The pins of the connectors are very fragile; make sure to push the four connectors evenly to avoid bending or breaking the pins.	

D. Make sure the pins of the connectors (pointed to by arrow) are no longer visible.	 

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP for active/passive board assembly.	05/08/2008	Barbara L. Clough
		Checked by AS on 2/19/09 OK	02/19/09	Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A5
Light Module Molding

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough Alan Stockdale			
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPs	Additional Documents
A1-3 Driver Board	T1-9 Visual Inspection of Light Module 1	A5 Appendix A
A1-4 LED Board	T1-10 Visual Inspection of Light Module 2	
	T8 Functional Testing	
	T9 Spectrometry Testing	
	T10 Optical Fluence 1 Testing	
	T11 Optical Fluence 2 Testing	

1. PURPOSE

The purpose of this document is to outline the procedures for light module molding for the clinical use FLARE™ (Fluorescence-Assisted Resection and Exploration) imaging system for the Frangioni Laboratory.

2. SCOPE

This procedure applies to all personnel assembling the FLARE™ imaging system.

3. POLICIES AND RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

The following forms must be complete and kept in the master device file.

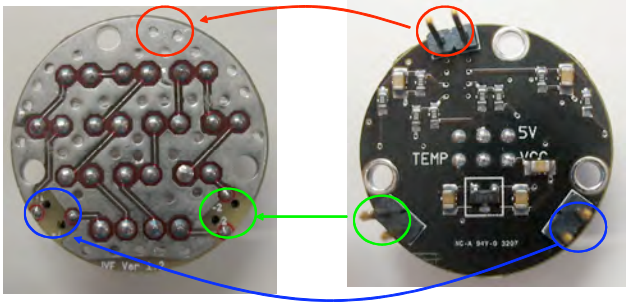
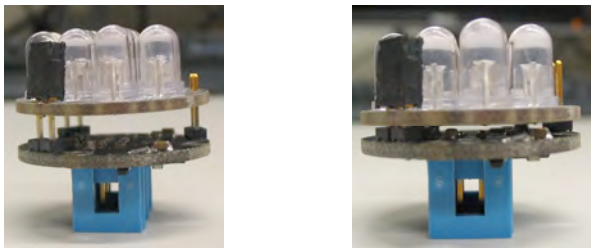
T1-9 Appendix A Light Module 1 Testing Form
T1-10 Appendix A Light Module 2 Testing Form
T8 Appendix A Functional Testing Form
T9 Appendix A Spectrometry Testing Form
T10 Appendix A Optical Fluence 1 Testing Form
T11 Appendix A Optical Fluence 2 Testing Form

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A1-3 Driver Board
A1-4 LED Board
A5 Appendix A Molding Fabrication Assembly/Instructions

6. PROCEDURES

Steps	
A. Boards are assembled according to SOP A1-3 Driver Board Fabrication and Assembly and SOP A1-4 LED Board Fabrication and Assembly. Assembled boards are sent to BIDMC to be put together.	
B. Insert the assembled LED Board into the assembled Driver Board. Pay attention to inserting the three, 2-pin headers on the assembled Driver Board into the appropriate holes on the assembled LED Board. Only one positioning is possible. Make sure that the components of the two boards are not touching.	*Top of assembled LED board* *Bottom of assembled driver board*  Side view during insertion Side view after insertion 
C. After the assembled LED Boards and Driver Boards are put together, they are tested for the following: • Visual (SOP T1-9) • Functional (T8) • Spectrometry (T9) • Fluence 1 (T10) • Fluence 2 (T11) is also performed to gather spec information Forms Required: Complete T1-9 Appendix A Light Module 1 Testing Form, T8 Appendix A Functional Testing Form, T9 Appendix A Spectrometry Testing Form, T10 Appendix A Optical Fluence 1	

Testing Form, and T11 Appendix A Optical Fluence 2 Testing Form. These forms are kept in the master device file.	
D. After the boards are fitted together according to procedure, they are sent out for molding with specific notes [SOP A5 Appendix A]. Forms Required: F1 Shipping and Receiving. These forms are to be kept in the master device file.	
E. Upon receipt of molded LED Modules, the following tests are performed: • Visual (SOP T1-10) • Functional (T8) • Optical spectral (T9) • Fluence 1 (T10) • Fluence 2 (T11) is also performed to gather spec information Forms Required: Complete T1-10 Appendix A Light Module 2 Testing Form, T8 Appendix A Functional Testing Form, T9 Appendix A Spectrometry Testing Form, T10 Appendix A Optical Fluence 1 Testing Form, and T11 Appendix A Optical Fluence 2 Testing Form. These forms are kept in the master device file.	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A5 for Light Module molding.	04/14/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A5 Appendix A
Molding Fabrication/Assembly Instructions

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A5 Light Module Molding	None	None

These instructions are to be included in the Molding Fabrication/Assembly package for the Light Module when sent to Albright Technologies.

1. Molding needs to be smooth without bumps and without any visual imperfection.

2. Modules are painted according to their wavelength:
    a. Red for 670 nm red light module
    b. Purple for 760 nm NIR light module
    c. Green for 525 nm green light module
    d. Blue for 470 nm blue light module
    e. White for white light module

3. LED lenses need to be clean from any molding material.

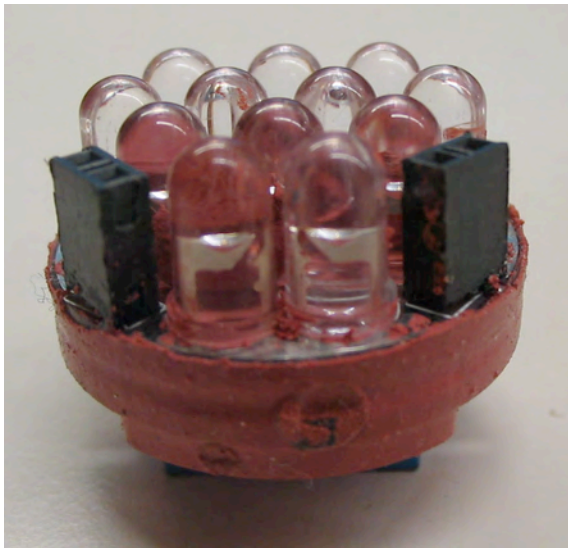
4. Boards need to be clean from any contamination.

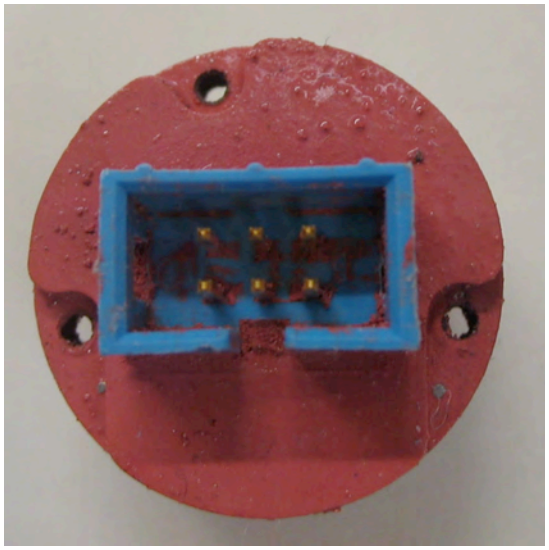
5. ICs are electro-statically very sensitive and the person handling the ICs needs to be grounded for proper handling.

6. Modules will be visually inspected after assembly. Special attention should be paid to the above mentioned features.

7. Special attention should be taken to protect the modules during shipment.

Example of final molding of version 1.2 modules (example with red module):

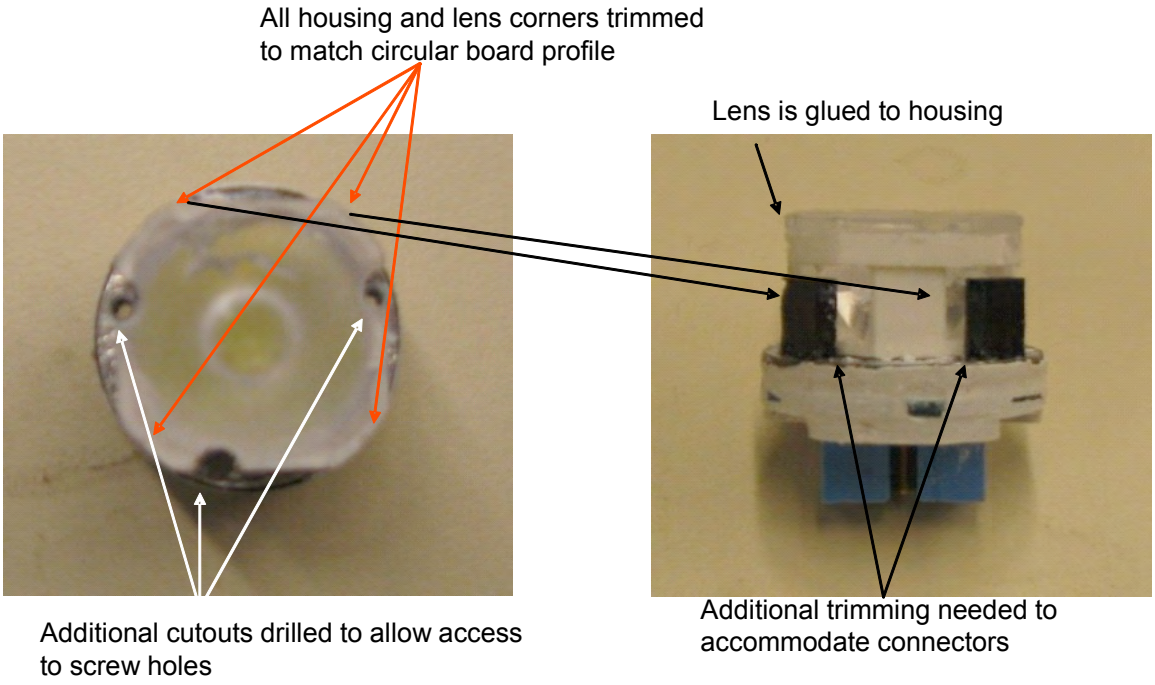




Additional Assembly for Rebel LED boards

The Rebel LED boards need to have a plastic housing and a lens added, which are both added by Albright prior to molding. The housing and lens require some alterations prior to assembly (also performed by Albright), which are detailed below:

- LEDiL RE Square Diffuser – RES-D (+-9 degrees) – 1 per board.
- Corners cut on lens and holders so that profile will match that of Rebel LED PCB.
- Lens holder has adhesive backing – remove and press holder into place.
- Use epoxy to secure lens into place ensuring that none gets on optical surface notes refer to diagram below).



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A5 Appendix A Molding Fabrication/Assembly Instructions for A5 Light Module Molding	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A6
LED Ribbon Cable

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Alan Stockdale	03/16/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	T12 Cable Testing	None

1. PURPOSE

The purpose of this document is to outline the procedures for the LED Ribbon Cable fabrication used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the LED Ribbon Cable for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

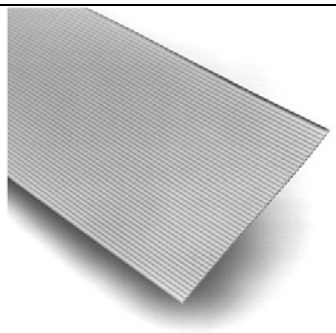
4. FORMS

T12 Appendix A Cable Testing Form

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

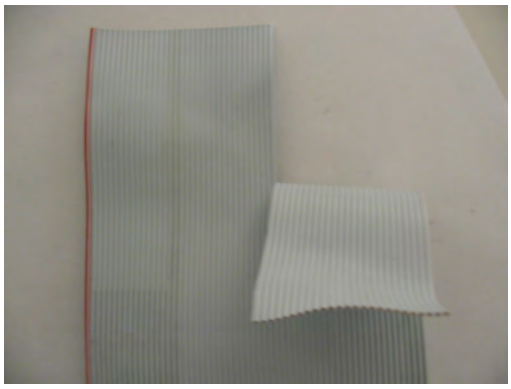
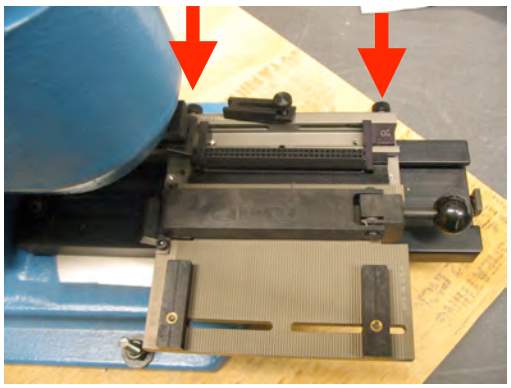
Name	Manufacturer	Part #	Qty.	Picture
60-pin crimp ribbon cable connector	Tyco Electronics	1-1658621-1	4	
40-pin crimp ribbon cable connector	Tyco Electronics	1658621-9	4	

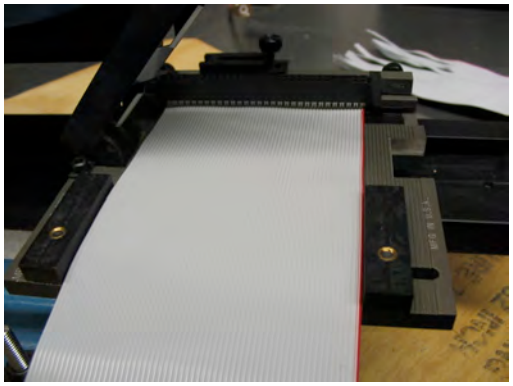
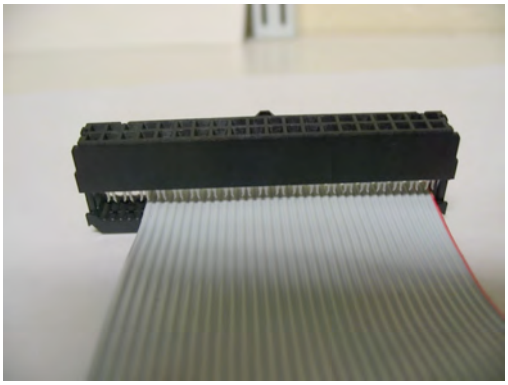
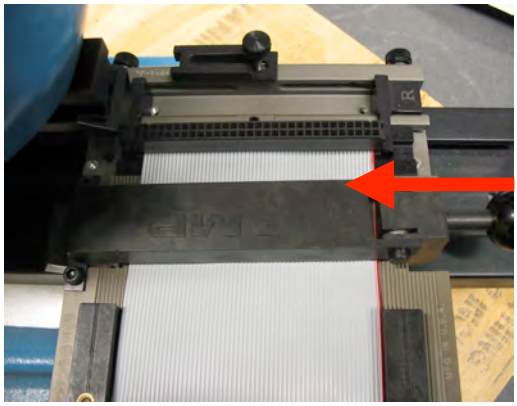
Tyco 6-pin crimp connector	Tyco Electronics	1-1658528-0	4	
3M™ Round Conductor Flat Cable, 3801 Series, Standard Version, 3801/60, 100 ft.	3M	3801/60 (100')		
EMI Shield Beads (43 ohm @ 100 MHz)	Fair-Rite	2643002402	76	
Manual Arbor Press	Tyco Electronics	91085-2		
Universal Base Assembly	Tyco Electronics	768338-1		

Connector Specific Kit	Tyco Electronices	768341-1		
Craftsman 9-1/2 in. pliers, arc joint	Craftsman	45381		
Scissors				

6. PROCEDURES

NOTE: There are 8 connectors that fit into the passive board; 4 are 40-pin connectors and 4 are 60-pin connectors.

Step 1: Inserting the cable into the connectors	
A. To build the 40-pin connectors, take the 60-wire cable and count out 35 wires (starting from the red line). Tear the able at this point, and cut the 35-wire cable 8.5 inches long. 35 wires are wanted as only seven modules are run off these connectors, and each connector requires five pins. The 60-pin cables have 12 modules running off of them; so all 60 wires are needed. For that reason, no tearing of the cable is needed; simply cut it at 6.5 inches.	
B. Insert the connector into the slot on the press as shown. Use the screws pointed to by the arrows to adjust the size of the slot. The side of the connector that has the middle piece that juts out should be as shown.	

C. Insert the cable into the connector as shown. The red line should be in the right most slot. Make sure that the pins are well aligned over the cable; if not, they will cut the cables in half instead of separating the cables from one another.	
C. For the 40-pin connector, only 35 of the 40 pins are used. This step should look like this, with the 5 pins to the left free (Pin 1 is to the left in the picture).	
D. Close the lock down to hold the cable firmly in place.	

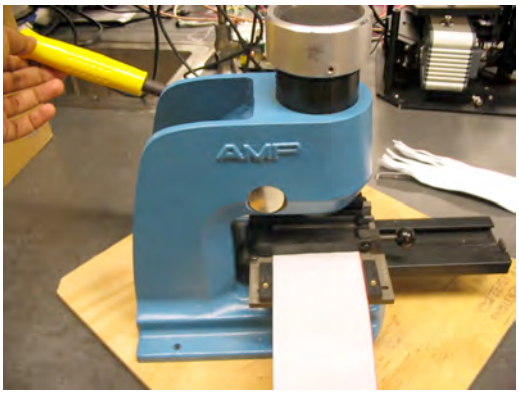
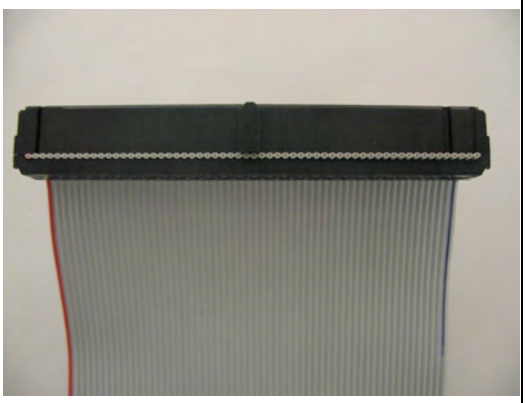
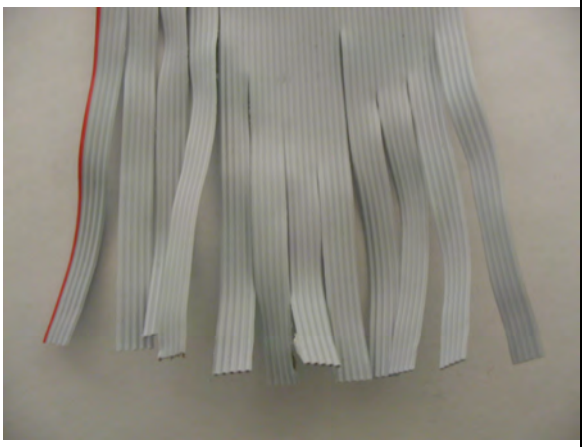
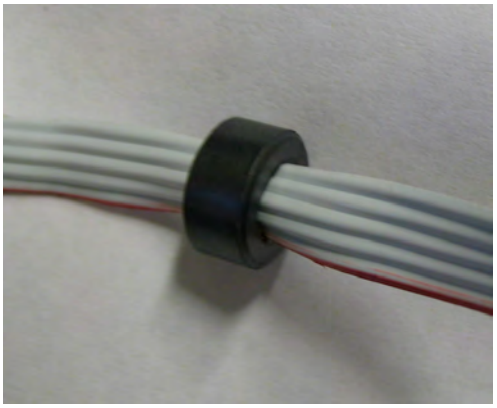
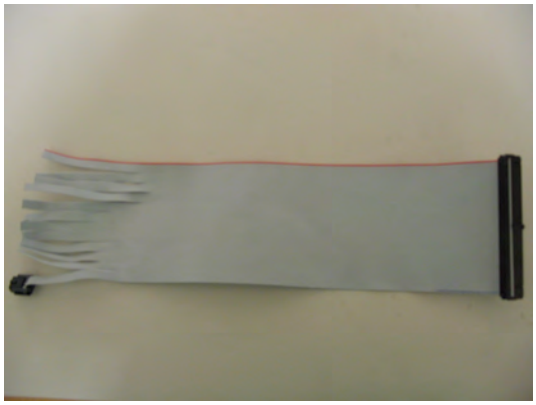
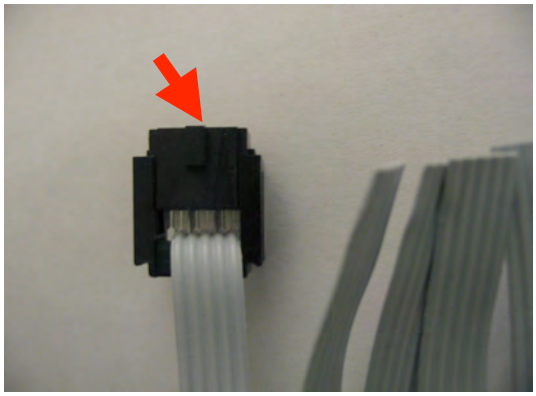
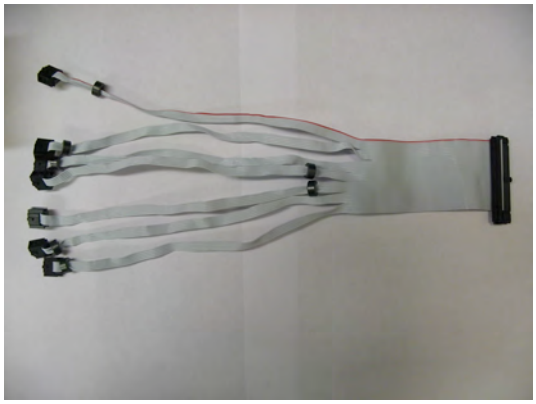
E. Rotate the yellow lever clockwise to press down on the connector; continue rotating until the pins fully enter the cable.	
F. The connector should look as pictured; if pins are still visible, try again with the press..	
Step 2: Adding 6-pin connectors	
A. At the other end of the connector, tear the cable in increments of 5 wires. For the 40-pin connectors, that should give seven 5-wite strips, and the 60-pin connectors should give 12. i. Each of the 5-wire strands needs to be cut according to Table 1 below. ii. The lengths go from left to right on the cable; for example, for connector 1, the first length (5.57 inches) corresponds to the 5-wire strand with the red stripe. iii. Because the cable was initially cut to 8.5 inches, that means 2.75 inches have to be cut off the strand. The next strand to the right must be cut to 6.25 inches, meaning 2.25 inches need to be removed, and so on. iv. The number in brackets (e.g. m18) in the table refers to the light module to which that strand will be connected.	

Table 1.

Connector:	**1**	**2**	**3**	**4**	**5 (m9)**	**6(m22)**	**7(m68)**	**8**
Type:	40-pin	40-pin	40-pin	40-pin	60-pin	60-pin	60-pin	60-pin
Length 1:	5.75 (m18)	7.25 (m37)	7.25 (m40)	5.50 (m59)	5.50 (m9)	6.50 (m22)	5.50 (m68)	6.50 (m55)
Length 2:	6.25 (m27)	8.00 (m38)	8.00 (m39)	6.25 (m50)	5.50 (m17)	6.00 (m13)	5.50 (m60)	5.50 (m64)
Length 3:	7.00 (m28)	6.25 (m43)	6.25 (m34)	7.00 (m49)	5.00 (m8)	6.00 (m21)	5.00 (m69)	5.00 (m73)
Length 4:	7.75 (m29)	7.00 (m44)	7.00 (m33)	7.75 (m48)	6.00 (m25)	5.00 (m4)	6.00 (m52)	6.00 (m56)
Length 5:	8.50 (m30)	7.75 (m45)	7.75 (m32)	8.50 (m47)	5.50 (m16)	5.50 (m12)	5.50 (m61)	5.50 (m65)
Length 6:	5.75 (m35)	8.50 (m46)	8.50 (m31)	5.50 (m42)	5.00 (m7)	6.00 (m20)	5.00 (m70)	5.00 (m74)
Length 7:	6.50 (m36)	5.75 (m51)	5.50 (m26)	6.50 (m41)	6.00 (m24)	5.00 (m3)	6.00 (m53)	6.00 (m57)
Length 8:					5.50 (m15)	5.50 (m11)	5.50 (m62)	5.50 (m66)
Length 9:					5.00 (m6)	6.00 (m19)	5.00 (m71)	5.00 (m75)
Length 10:					6.00 (m23)	5.00 (m2)	6.00 (m54)	6.00 (m58)
Length 11:					6.00 (m14)	5.50 (m10)	5.50 (m63)	5.50 (m67)
Length 12:					5.50 (m5)	5.50 (m1)	5.50 (m72)	5.50 (m76)

B. Place a ferrite bead on each of the 5-wire strands.



C. Each of the 5-wire strips will be connected to a 6-pin crimp connector. To determine the orientation of the 6-pin connector, the cable should be laid flat as show, with the jutting portion facing up.	
D. The crimp connector should have the jutting portion facing up (as indicated by the arrow). The 5-wire strip should go to the right-most 5 pins (the 6th is unused). Using pliers, clamp down on the connector until the pins are no longer visible.	
E. The end result should be like the cable pictured. Perform T12 Cable Testing. Form Required: Complete T12 Appendix A Cable Testing Form; this form is to be kept in the master device file.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A6 LED Ribbon Cable	03/16/2009	Alan Stockdale
V1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A7
Head DAQ Board Wiring

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough Alan Stockdale	01/04/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A8 Light Source Housing Assembly.	None	A7 Appendix A
A19 CA 1000		A7 Appendix B
		A7 Appendix C

1. PURPOSE

The purpose of this document is to outline the procedures for wiring the Head DAQ Breakout connections used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel wiring the Head DAQ Breakout connections for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A7 Appendix A Temperature Sensor Wiring
A7 Appendix B Passive Board 20-pin Header pinout
A7 Appendix C Passive Board to Breakout Panel Mapping
A8 Light Source Housing Assembly
A19 CA 1000

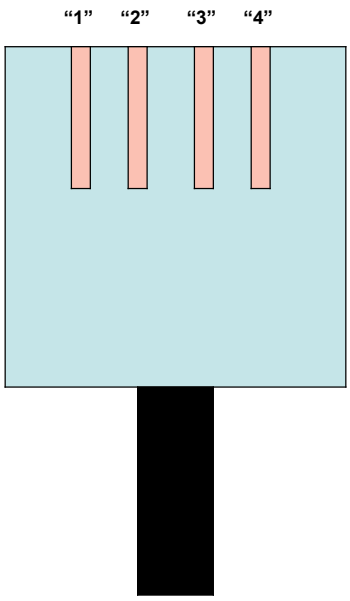
6. PROCEDURES

NOTE: This document should be used with A19 CA-1000 breakout document. The DAQ breakout panel that is mounted on the back of the back plate in the head and carries various signals from the CA-1000 that is in the cart. The appropriate connections in the head are wired to this panel, such as motors, sensors, passive board, etc. The breakout panel has 68 pins, each of which can represent a different signal for a particular device (see SOP A19 CA 1000, board #3 pinout). Wiring of some of these devices is discussed below.

1. Temperature Sensors	
A. There are three temperature sensors mounted in the head. 1. On the back plate 2. On the cold plate 3. Suspended in air in the head	
B. Each sensor has 3 wires: 5v, gnd, and Vout. Vout is the signal that represents temperature output.	
C. 5 volt and ground of the 3 temp sensors can be connected to the same terminals on the DAQ break out panel (see A7 Appendix A or A19 CA-1000).	
D. The output signals of these sensors are wired to separate terminals – pins 15-17 (see A7 Appendix A or A19 CA-1000).	
E. For TEMP sensors, use 3-wire SAMTEC cable. The color coding is as follows: • Brown → 5v • Red → GND • Orange → TEMP signal	
F. There are two holes that the temperature sensors screw into: On the back plate (upper left of LV breakout panel) and on the cooling plate. Use 2-56 by 1/4" screws.	
2. Passive Board	
A. There are 19 wires coming/going to a 20-pin connector (Samtec MMSS-10-26-S-36.00-D [U166]) on the passive board. The designations are shown in A7 Appendix B.	
B. A7 Appendix C refers to connections in the CA-1000 as a reference for the connections being made on the Head DAQ breakout board.	
3. Motor Connections	
A. Both motor control boards are connected to the DAQ I/O through phone cables. The cables are cut to about 1 inch in length and then stripped so that the wire can be inserted into the screw connections. The diagram below shows the connections. Wire colors are not specified as wire colors can vary. Motor 1 is designated as the	

bottom board, Motor 2 the top board.

Motor # / Cable pin #	DAQ I/O board connector
M1-1	J1
M1-2	J2
M1-3	-
M1-4	J3
M2-1	J5
M2-2	J6
M2-3	-
M2-4	J7



View of bottom of phone connector

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Head DAQ Board wiring	01/04/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A7 Appendix A
Temperature Sensor Wiring

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A7 Head DAQ Board Wiring	None	None

Table 1. Temp Sensor Wiring (in SOP A19 CA-1000)

Head DAQ breakout connection	Destination in DAQ	CA-1000 connection	General description
J13	DAQ +5V	B1_14	TempSensor1_5V, TempSensor2_5V, TempSensor3_5V, TempSensor4_5V
J14	DAQ AGND	B1_67	TempSensor1_Gnd, TempSensor2_Gnd, TempSensor3_Gnd, TempSensor4_Gnd
J15	DAQ AI 0	B1_68	TempSensor1_Sense
J16	DAQ AI 1	B1_33	TempSensor2_Sense
J17	DAQ AI 2	B1_65	TempSensor3_Sense

5 volt and ground of the 3 temp sensors can be connected to the same terminals on the DAQ break out panel (pin J13 – see Table 1 or SOP A19 CA-1000).

The output signals of these sensors are wired to separate terminals — pins 15-17. (See Table 1 or SOP A19 CA-1000.)

For TEMP sensors, use 3-wire SAMTEC cable.
The color coding is as follows:

- Brown ⇒ 5 V
- Red ⇒ GND
- Orange ⇒ TEMP signal

There are two (2) holes that the temperature sensors screw in to on the back plate and the cooling plate: the backplate (upper left of LV breakout panel) and the second (on cooling plate). Use 2-56 by ¼" screws.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A7 Appendix A Temperature Sensor Wiring for SOP A7 Head DAQ Board Wiring	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A7 Appendix B
Passive Board 20-pin Header Pinout

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A7 Head DAQ Board Wiring	None	None

Passive Board

There are 19 wires coming/going to a 20-pin connector (Samtec MMSS-10-26-S-36.00-D [U166]) on the passive board. The designations are shown in the table below:

Table 1: Passive Board 20-pin Header (U166) Pinout

Pin#	Label	Description	Head DAQ breakout connection
U166: Pin1	C1-A0	C1 Mux: control 0	**J32**
U166: Pin2	DAQ-	DAQ board ground	**J46**
U166: Pin3	C2-A0	C2 Mux: control 0	**J34**
U166: Pin4	C1-A1	C1 Mux: control 1	**J31**
U166: Pin5	C3-A0	C3 Mux: control 0	**J36**
U166: Pin6	C2-A1	C2 Mux: control 1	**J33**
U166: Pin7	C4-A0	C4 Mux: control 0	**J38**
U166: Pin8	C3-A1	C3 Mux: control 1	**J35**
U166: Pin9	C5-A0	C5 Mux: control 0	**J40**
U166: Pin10	C4-A1	C4 Mux: control 1	**J37**
U166: Pin11	RXO	Serial port: RX0	**J41**
U166: Pin12	C5-A1	C5 Mux: control 1	**J39**
U166: Pin13	DTR	Serial port: DTR	**J50**
U166: Pin14	RTS	Serial port: RTS	**J42**
U166: Pin15	TXO	Serial port: TX0	**J45**
U166: Pin16	DB9-	Serial port: Ground	**J44**
U166: Pin17	RST	uController: RST	**J47**
U166: Pin18	TEMP	Temp Out	**J49**
U166: Pin19	PRG	uController: PRG	**not connected**
U166: Pin20		Un-used	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A7 Appendix B Passive Board 20-pin Header Pinout for SOP A7 Head DAQ Board Wiring	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A7 Appendix C
Passive Board to Breakout Panel Mapping

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A7 Head DAQ Board Wiring	None	None

Table 1. Passive board to breakout panel wire mapping

This table refers to connections in the CA 1000 as a reference for the connections being made on the Head DAQ breakout board.

Board_pin#	Destination	Connects to		General description		Group
B3_31	DAQ P1.0	B1_11	P	C1_ON/OFF	C1: A1	Passive Board
B3_32	DAQ DGND	B1_12	G	C1_DGND	C1:A0	Passive Board
B3_33	DAQ P1.1	B1_10	P	C2_ON/OFF	C2:A1	Passive Board
B3_34	DAQ DGND	B1_9	G	C2_DGND	C2:A0	Passive Board
B3_35	DAQ P1.2	B1_43	P	C3_ON/OFF	C3:A1	Passive Board
B3_36	DAQ DGND	B1_44	G	C3_DGND	CE:A0	Passive Board
B3_37	DAQ P1.3	B1_42	P	C4_ON/OFF	C4:A1	Passive Board
B3_38	DAQ DGND	B1_36	G	C4_DGND	C4:A0	Passive Board
B3_39	DAQ P1.4	B1_41	P	C5_ON/OFF	C5:A1	Passive Board
B3_40	DAQ DGND	B1_35	G	C5_DGND	C5:A0	Passive Board
B3_41	DB9 #3			Serial3_1	RXO	Passive Board
B3_42	DB9 #3			Serial3_2	RTS	Passive Board
B3_43	DB9 #3			Serial3_3	DTR	Passive Board
B3_44	DB9 #3			Serial3_4	DB9	Passive Board
B3_45	DB9 #3			Serial3_5	TX0	Passive Board
B3_46	DAQ DGND	B1_4		Passive Board Gnd		Passive Board
B3_47	DAQ P1.5	B1_6		Reset		Passive Board
B3_49	DAQ AI 10	B1_31		Temperature out		Passive Board

To connect the passive board to the DAQ breakout board, use the 20 cable SAMTEC connector. For the passive board wires from C1:A0 to C5:A1 wires, twist each A1-A0 pair. Make sure to trim the wires since they are very long (trim about 3”).

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A7 Appendix C Passive Board to Breakout Panel Mapping A7 Head DAQ Board Wiring	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A8
Light Source Housing Assembly

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough Alan Stockdale	06/11/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-1 Active Board	None	A8 Appendix A
A1-2 Passive Board		
A3 Jumper, Filter, LED Maps		
A3 Appendix B Mapping for Clinical Use OR A3 Appendix D Mapping for Research Use		
A4 Active-Passive Board		

Assembly		
A5 Light Module Molding		
A6 LED Ribbon Cable		

1. PURPOSE

The purpose of this document is to outline the procedures for assembling the full Light Source Housing used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the Light Source Housing for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

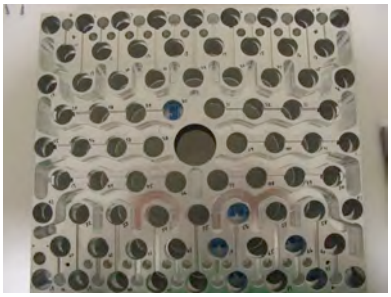
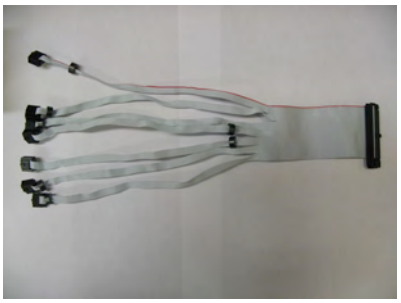
4. FORMS

There are no forms for this SOP.

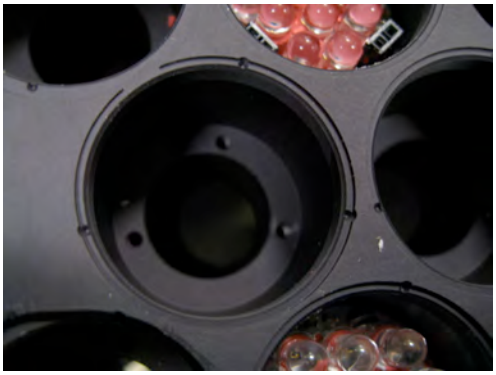
5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

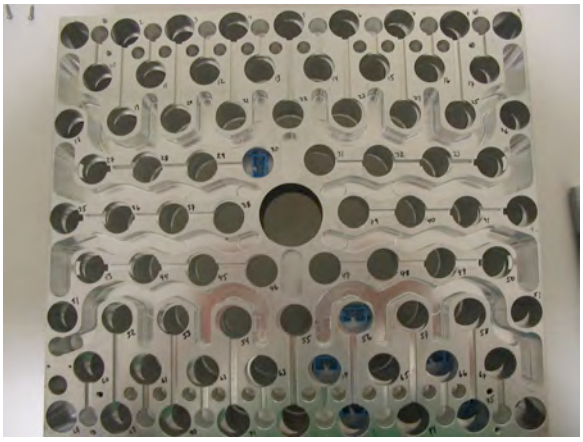
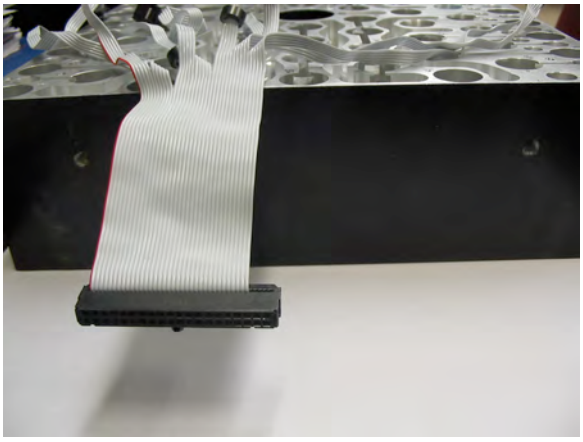
A1-1 Active Board
A1-2 Passive Board
A3 Jumper, Filter, LED Maps
A3 Appendix B Mapping for Clinical Use OR A3 Appendix D Mapping for Research Use
A5 Light Module Molding
A6 LED Ribbon Cable
A8 Appendix A List of Materials
A8 Appendix B Eight Cable Ribbon Assemblies
Cooling Plate
Cone
Filter Holding Tool

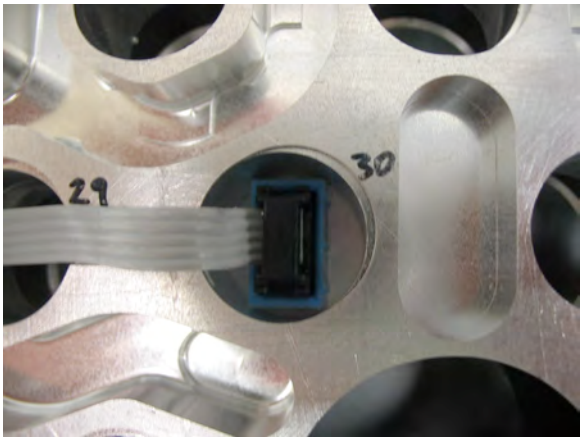
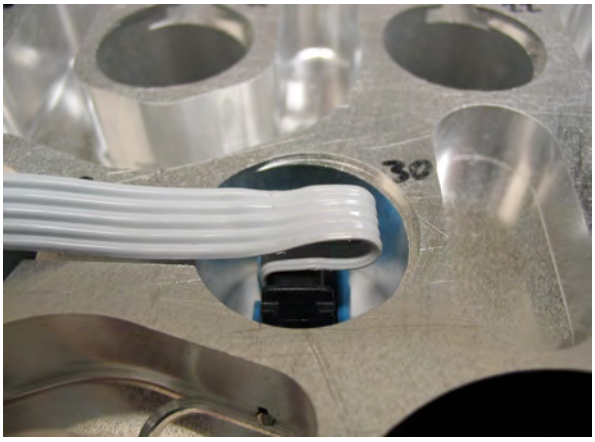
Name	Manufacturer	Part #	Qty.	Picture
Anodized Aluminum Housing	LAE Technology	Custom	1	
Ribbon cables (assembled in SOP A6 LED ribbon cable assembly)	Custom	Custom	8	
2-56 x 7/16 screws	McMaster-Carr	91783A080	228	
8-32 x ¾ screws	McMaster-Carr	91781A197	4	
4-40 x ¼ screws	McMaster-Carr	91772A106	8	

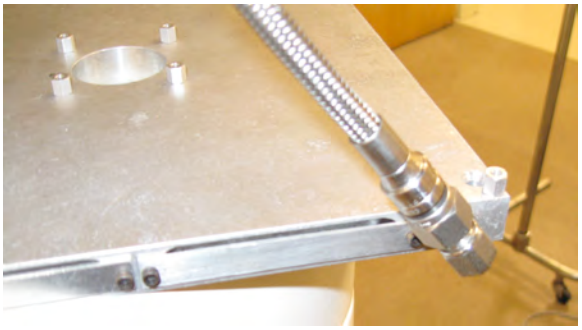
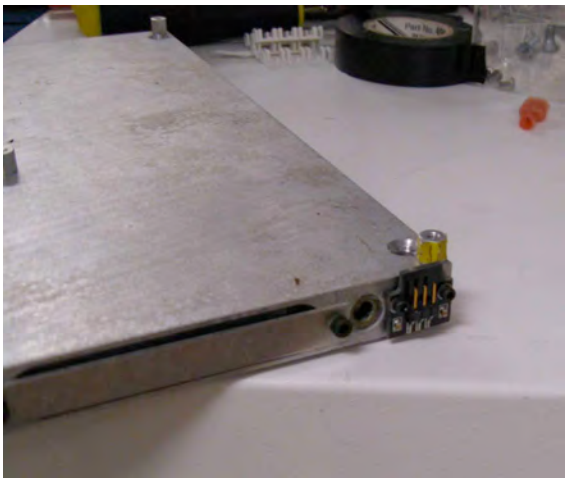
6. PROCEDURES

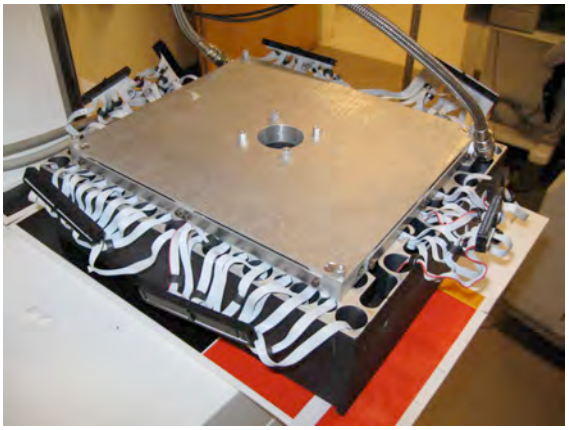
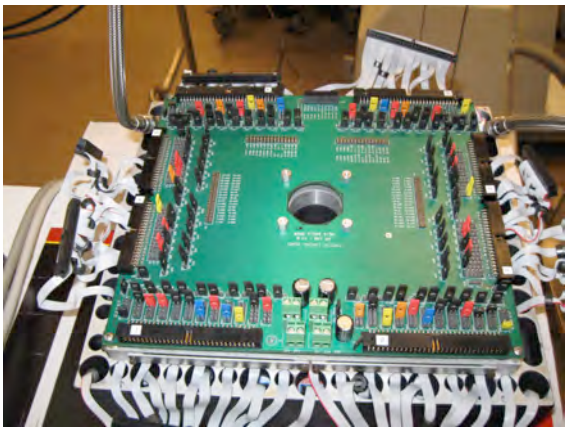
Step 1: Installing the LED Modules, Collimators, and Filters into the housing base	
A. Pick out the 76 LED modules and filters per the LED module diagram SOP A3 Jumper, Filter, LED Maps (Appendix B for Clinical use or Appendix D for Research),	
B. In each of the modules there are three holes; insert a 2/56 x 7/16 screw in each hole.	
C. To insert the modules into the housing, insert the modules into the holes in the housing. The notches at the top of the holes correspond to how the screws should line up.	
D. Once all of the modules are screwed in, insert the collimators on top of the NIR and red LED modules. There is only one orientation in which the collimators will fit.	

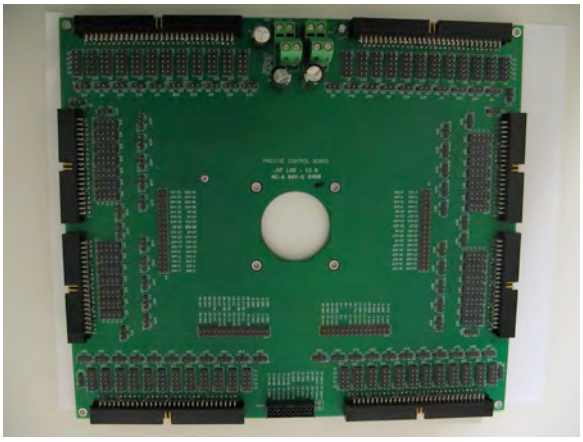
E. Press the collimators until they are firmly held on top of the modules, ensuring that they remain flat.	
F. Once all the collimators are in, the filters can be inserted. Use the filter removal tool to insert the filters.	
G. The notches on the filters fit into the tool and hold the filter in place. Make sure to screw the filters into the housing completely.	
H. Attach the light cone to the filter side of the housing using four 2/56 x 7/16 screws.	

Step 2: Fitting the Ribbon Cables	
A. The eight ribbon cable assemblies need to be inserted in the back of the housing. The cables constructed should be numbered according to the table in A8 Appendix B.	
B. With Module 1 in the top left, place the ribbon cables in the positions shown. Attach the 6-pin connector to each of the modules as numbered in the table in A8 Appendix B. Pass the able through the trough, making sure to leave a small amount of cable.	
C. When placing the connectors, make sure the jutting part is facing down as shown.	

D. Insert the 6-pin connector firmly into the back of the light module it corresponds to (according to A8 Appendix B). Insert all connectors corresponding to the same 40-pin or 60-pin connector before moving on to the next step.	
E. Fold the strands as shown, to leave a bit of slack so that the module can be pulled out slightly from the front of the housing without disconnecting the cable. The amount of slack should be the maximum without the cable sticking out of the hole.	
F. Pass the strands through the troughs that lead back to the connector. Always start with the ones closest to the edge of the housing first, as the farther ones might have to pass over the strands of the closer ones inside of the troughs.	

Step 3. Placing the Cooling Plate on the Housing	
NOTE: The cooling plate is the next part to be inserted. At this point the Thermocube should already have been tested (SOP A21 Thermocube Preinstallation Test), as the cooling plate needs to be attached to the cooling cables.	
A. Ensure that the angles of the two elbows are correct; they should be a 30-degree angle from the top of the plate. The top of the plate is the side where the four screws are countersunk.	
B. On the top side, insert 1/4 inch standoffs into the eight 4-40 screw holes. The image shows the angle at which the elbows are adjusted, along with the 1/4 inch standoffs.	
C. Place the cooling plate on top of the housing, with the elbows pointing upward. For orientation, the elbows should be on the end of the housing where Module 1 is.	
D. Install 1 temperature sensor board. The location is on the end opposite to the elbow. There are two 2-56 tapped holes that are used to mount the temp sensor.	

E. Use the 8/32 x 3/4 screws to connect the cooling plate in to the housing.	
Step 4. Placing the Active and Passive Boards on the Cooling Plate	
A. With the cooling plate attached to the housing, all that is left is to connect the passive and active boards. Line up the passive board with the housing (e.g. m1 on the passive board should be in the same corner as Module 1 in the housing).	
B. Use eight (8) 4-40 screws to attach the passive board to the standoffs on the cooling plate. Install four more standoffs into the four central holes on the passive board.	

C. Plug the Ribbon Cables into the Passive Board. They should line up as shown in the picture.	
D. Plug the Active Board onto the Passive Board (see SOP A4 Active/Passive Board Assembly). There are four headers in the middle of the passive board that fit into the connectors at the bottom of the passive board. Align them, and then push the active board gently until completely connected.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP A8 Light Source Housing Assembly.	06/11/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A8 Appendix B
Eight Cable Ribbon Assemblies

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A8 Light Source Housing Assembly	None	None

The eight ribbon cable assemblies from SOP A6 need to be inserted in the back of the housing. The cables constructed should be numbered as follows:

Connector:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Type:	40-pin	40-pin	40-pin	40-pin	60-pin	60-pin	60-pin	60-pin
1. Length: **Module:** **(red stripe)**	5.75 (m18)	6.25 (m37)	5.75 (m40)	6.25 (m59)	5.50 (m9)	6.00 (m22)	5.00 (m68)	6.50 (m55)
2. Length: **Module:**	6.25 (m27)	8.00 (m38)	6.25 (m39)	8.00 (m50)	5.50 (m17)	5.50 (m13)	5.50 (m60)	5.50 (m64)
3. Length: **Module:**	7.00 (m28)	6.25 (m43)	7.00 (m34)	6.25 (m49)	5.00 (m8)	6.00 (m21)	5.00 (m69)	5.00 (m73)
4. Length: **Module:**	7.75 (m29)	7.00 (m44)	7.75 (m33)	7.00 (m48)	6.50 (m25)	5.00 (m4)	6.00 (m52)	6.00 (m56)
5. Length: **Module:**	8.50 (m30)	7.75 (m45)	8.50 (m32)	7.75 (m47)	5.50 (m16)	5.50 (m12)	5.50 (m61)	5.50 (m65)
6. Length: **Module:**	5.75 (m35)	8.50 (m46)	5.75 (m31)	8.50 (m42)	5.00 (m7)	6.00 (m20)	5.00 (m70)	5.00 (m74)
7. Length: **Module:**	6.50 (m36)	5.75 (m51)	6.50 (m26)	5.75 (m41)	6.50 (m24)	5.00 (m3)	6.00 (m53)	6.00 (m57)
8. Length: **Module:**					5.50 (m15)	5.50 (m11)	5.50 (m62)	5.50 (m66)
9. Length: **Module:**					5.00 (m6)	6.00 (m19)	5.00 (m71)	5.00 (m75)
10. Length: **Module:**					6.50 (m23)	5.00 (m2)	6.00 (m54)	6.00 (m58)
11. Length: **Module:**					6.00 (m14)	5.50 (m10)	5.50 (m63)	5.50 (m67)
12. Length: **Module:**					5.50 (m5)	5.00 (m1)	5.50 (m72)	5.50 (m76)

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A8 Appendix A Eight Cable Ribbon Assemblies for SOP A8 Light Source Housing Assembly	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A9
Motor Mounting onto Lens Tube

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough	06/11/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	None	None

1. PURPOSE

The purpose of this document is to outline the procedures for Motor Mount to Lens Tube used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

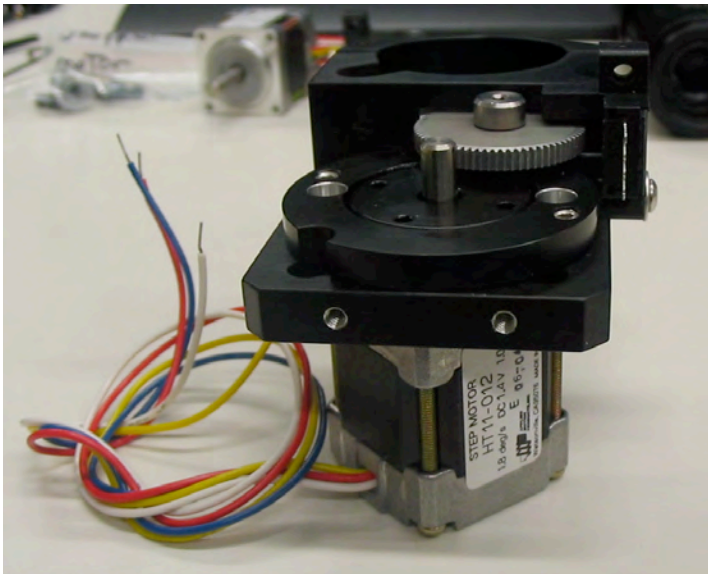
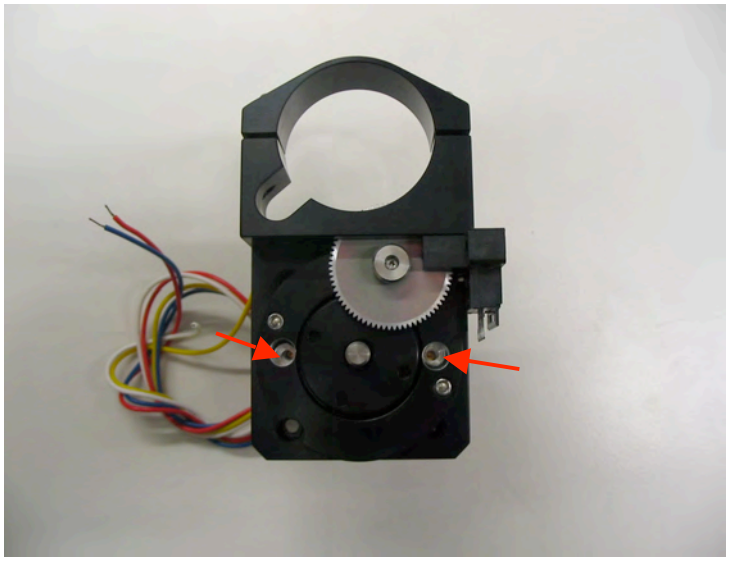
There are no forms for this SOP.

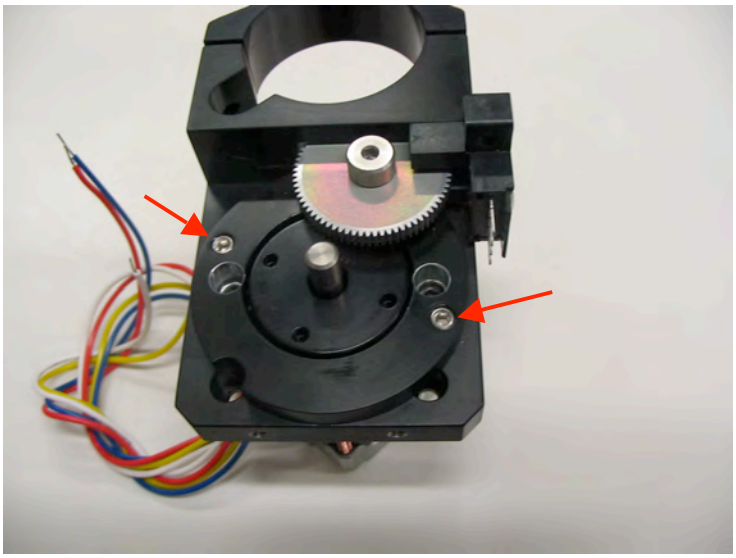
5. MATERIALS AND EQUIPMENT

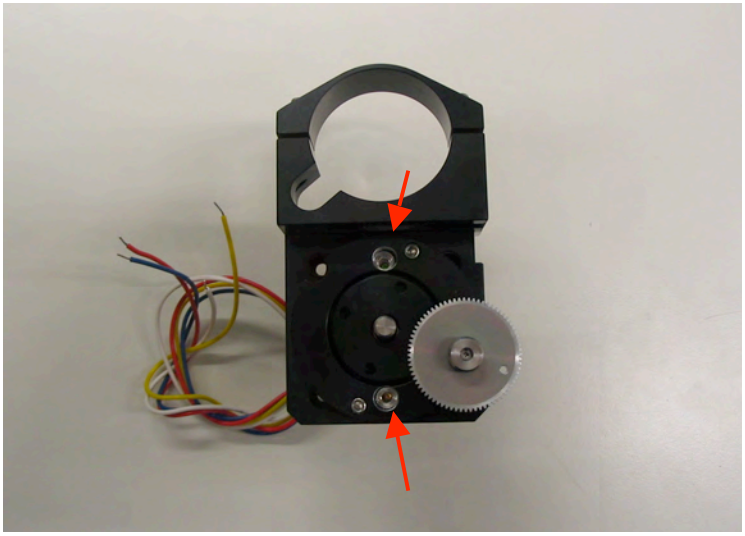
The following materials will be needed for completion of this SOP.

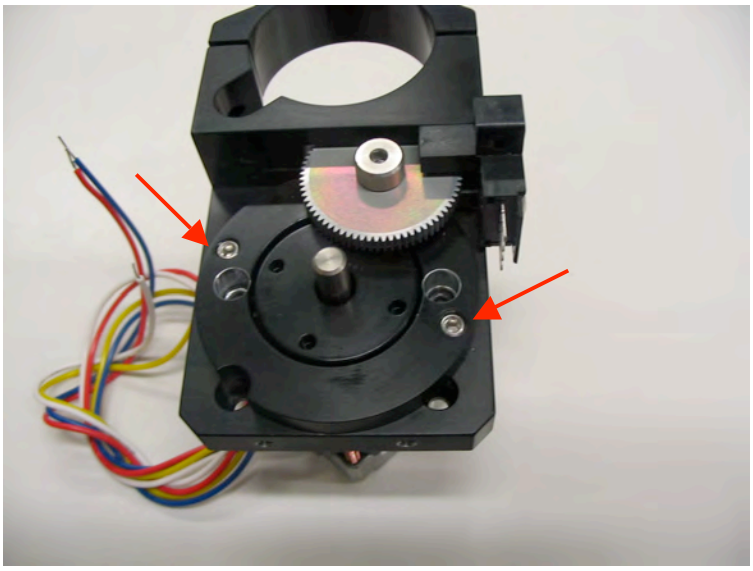
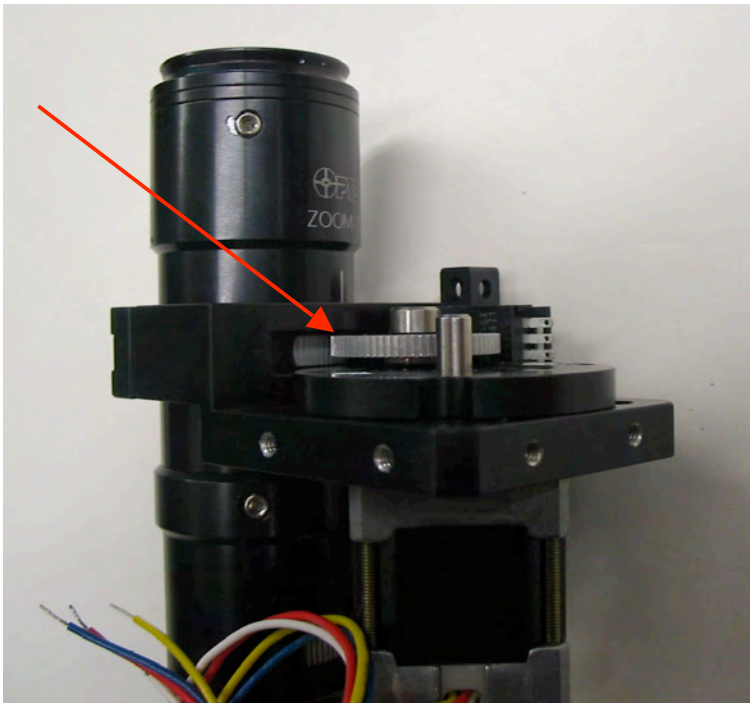
2 stepper motors
Optem zoom and focus lenses
2 motor brackets with sensors attached
Stepper motor hardware comprising 2 motor wheels and 8 hex cap screws

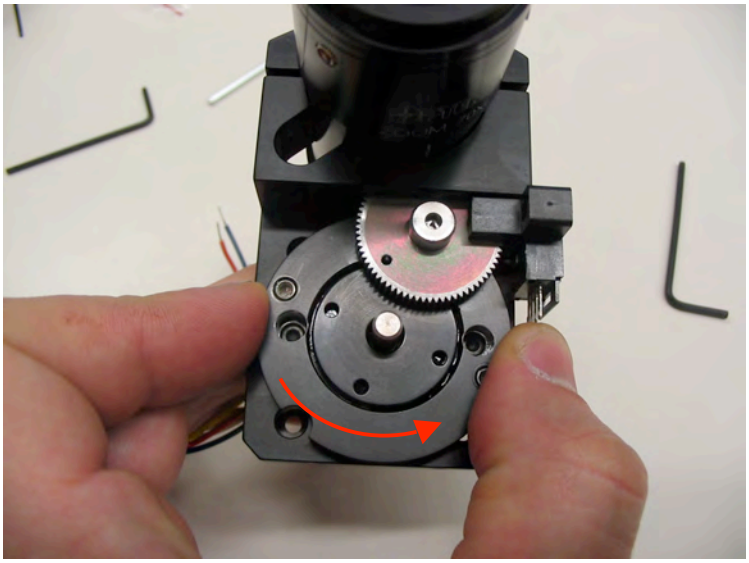
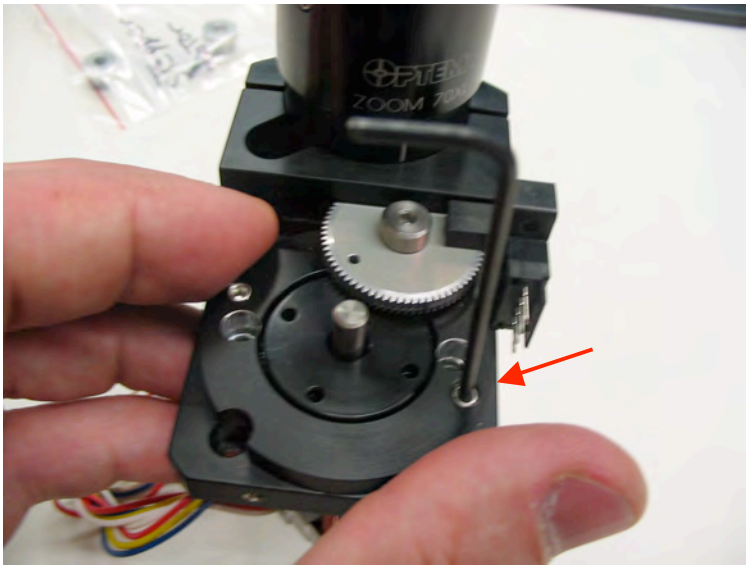
6. PROCEDURES

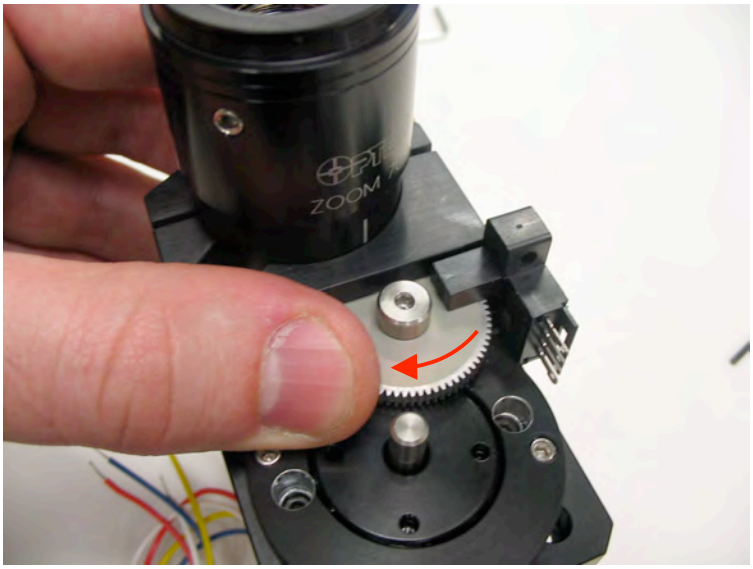
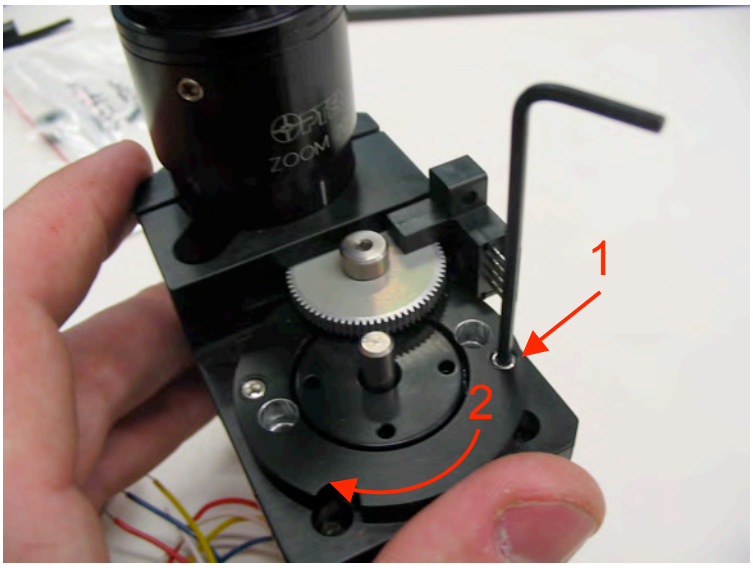
Steps	
A. Take one motor and one bracket and place the motor under the bracket.	
B. Align the holes in the bracket and the holes in the motor.	

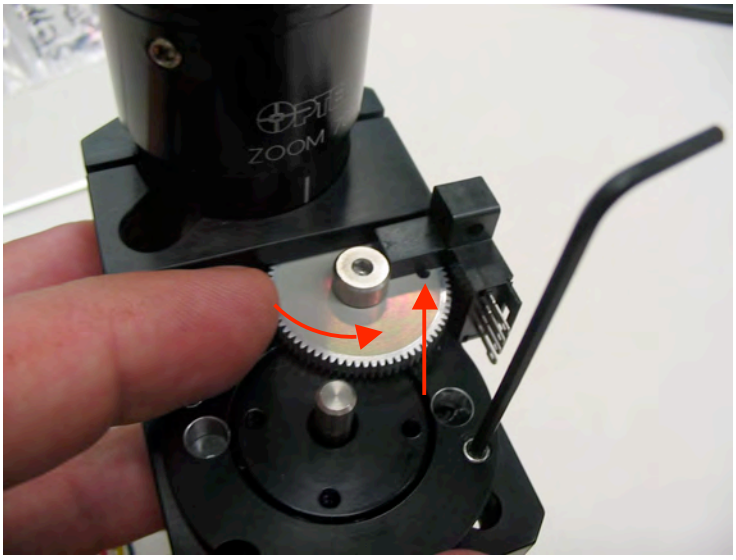
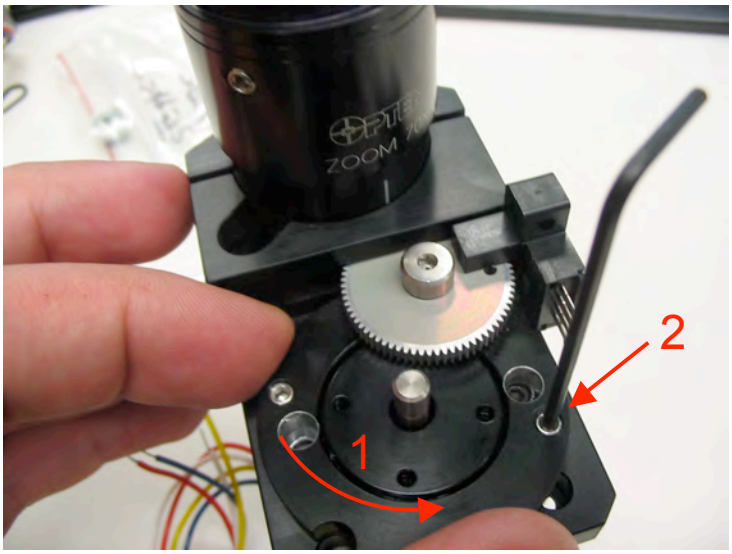
C. Insert and screw in two of the motor screws in these holes.	
D. Loosen the two screws indicated by the arrows.	
E. Rotate to align the 2 other holes to attach the motor to the bracket. Insert and screw in 2 of the motor screws into these holes.	

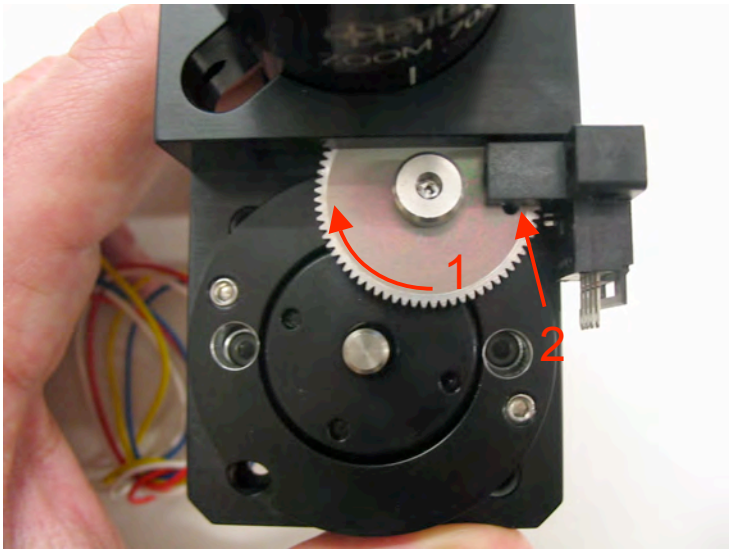
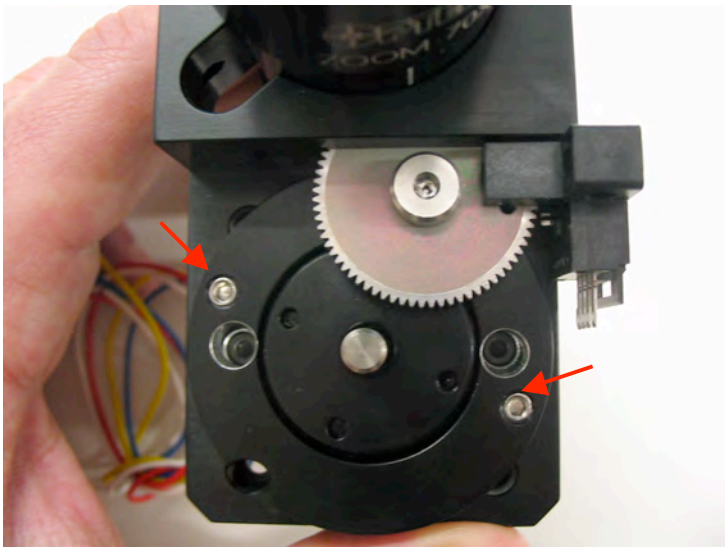
Note: you will need to unscrew the sensor to complete that operation.	
F. Make sure the lens wheels are aligned one with the other. If they are not, loosen the screws at the top of the section that is not aligned (three [3] screws for each zoom and focus). Rotate the section and tighten the screws.	

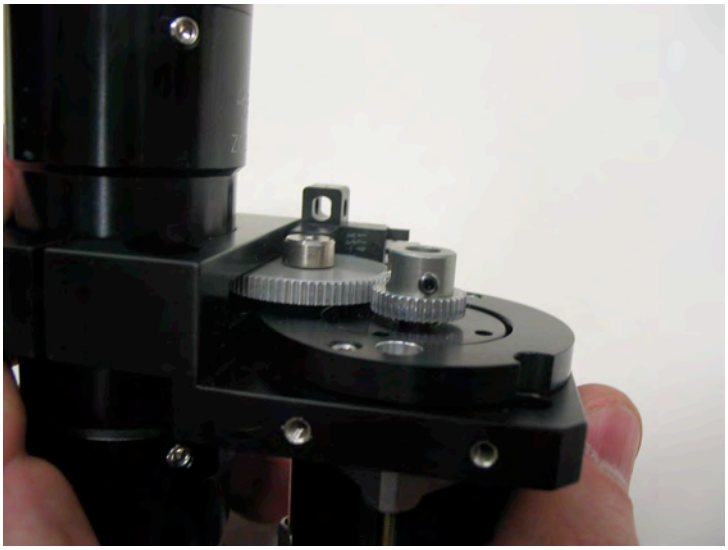
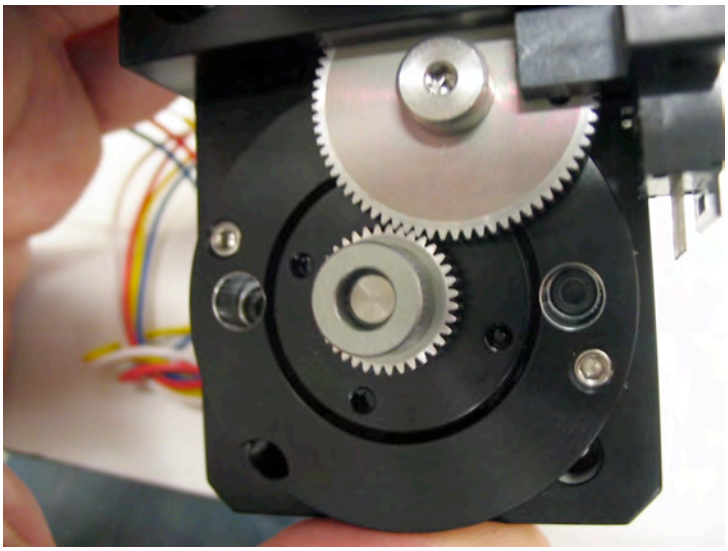
G. Loosen the screws indicated by the arrows.	
H. Insert the bracket in the top section, motor body down and screw in the bracket holder. Make sure the wheels are aligned.	

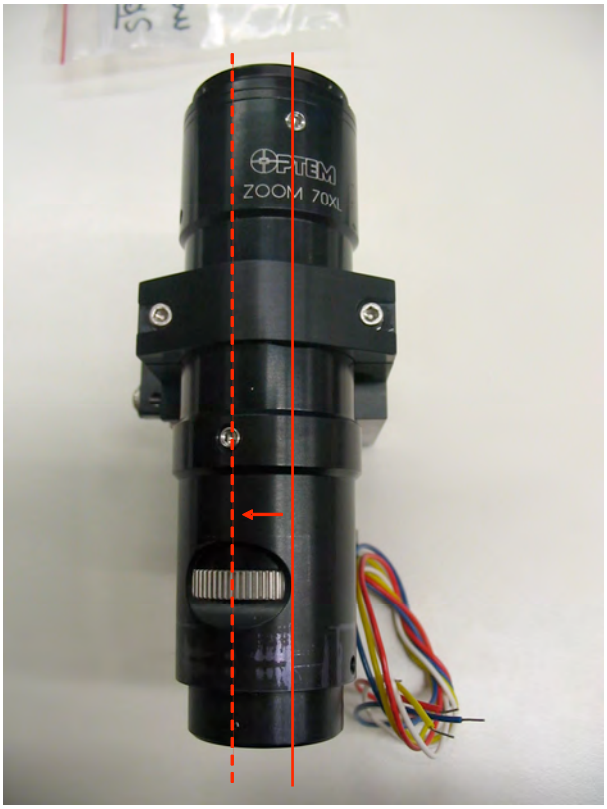
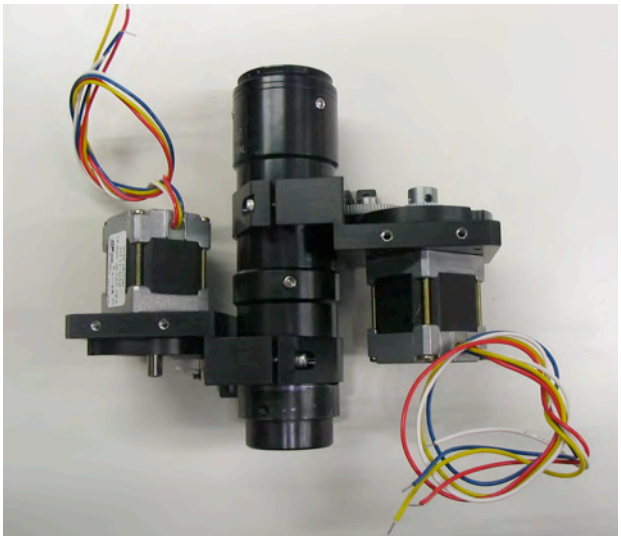
I. Rotate the bracket wheel plate and engage it into the lens wheel.	
J. Tighten only one (1) screw on the bracket wheel plate.	

K. Rotate the bracket wheel in the direction shown until the lens reaches the end of its travel.	
L. Loosen the screw on the bracket wheel plate and disengage the wheels.	

M. Rotate the bracket wheel in the direction shown until the hole passes the sensor edge.	
N. Engage the wheels together and tighten the screw on the bracket wheel plate.	

N. Rotate the wheel until the end of travel and check the hole alignment. It should be close to the one shown on the picture. If it is not correct, repeat steps until it is well aligned.	
O. Tighten both screws.	

P. Install the motor wheel as shown in the picture.	
Q. Make sure the motor wheel screw is in contact with the shaft and tighten the motor wheel screws.	

R. Rotate the bottom section slightly to the left as described in step F.	
S. Install the second motor on the bottom section as shown for the first motor and with the orientation as shown.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP A9 Motor Mount to Lens Tube	04/22/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A10
Full Head Assembly

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough Alan Stockdale	04/21/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A9 Motor Mount to Lens Tube		A10 Appendix A
A1-5 Temp Sensor Board		
A8 Light Source Housing Assembly		
A7 Head DAQ Breakout Connection		
A11 Motor Control Board Wiring		

A14 DC Power Delivery		

1. PURPOSE

The purpose of this document is to outline the procedures for the Full Head Assembly used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the Full Head for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There no forms for this SOP.

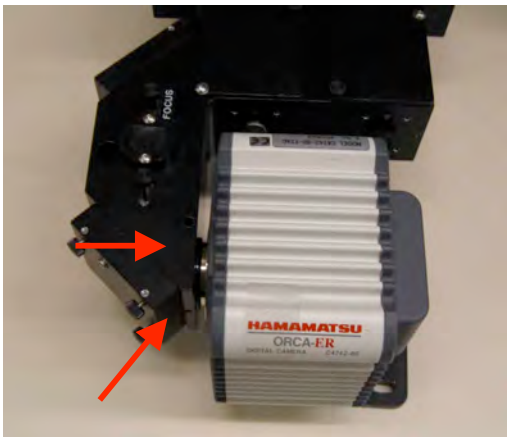
5. MATERIALS AND EQUIPMENT

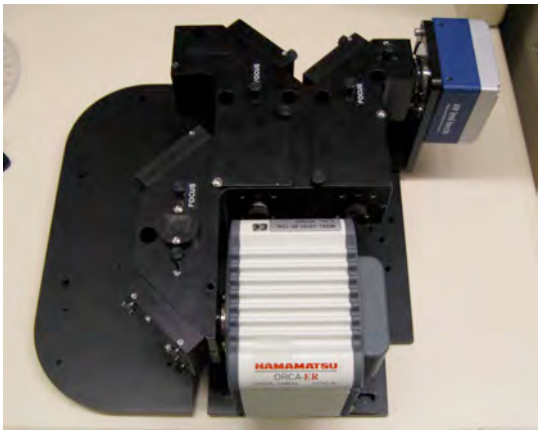
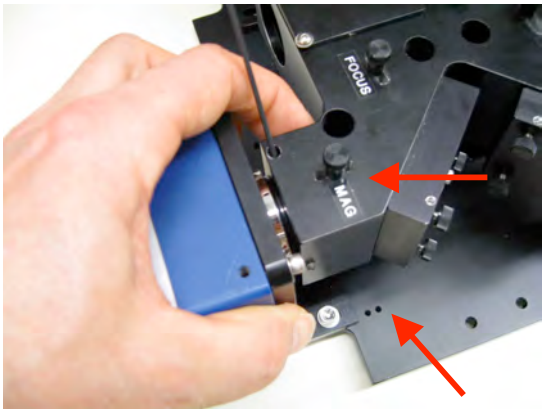
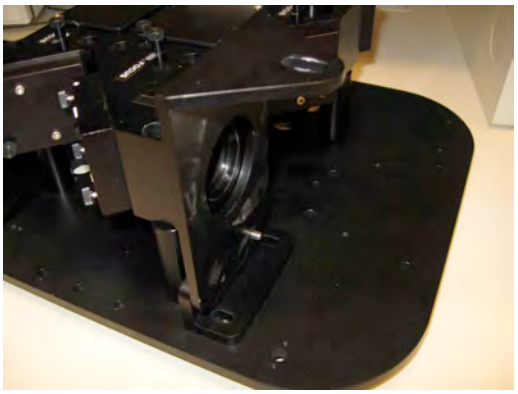
The following materials will be needed for completion of this SOP.

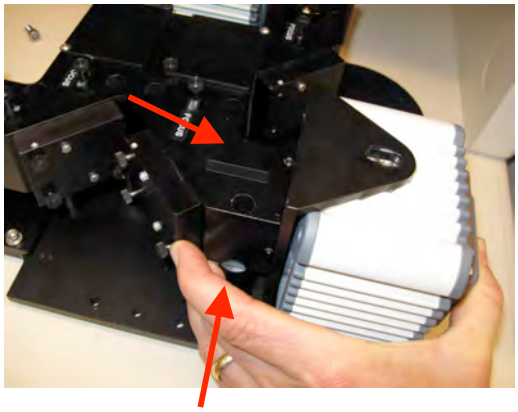
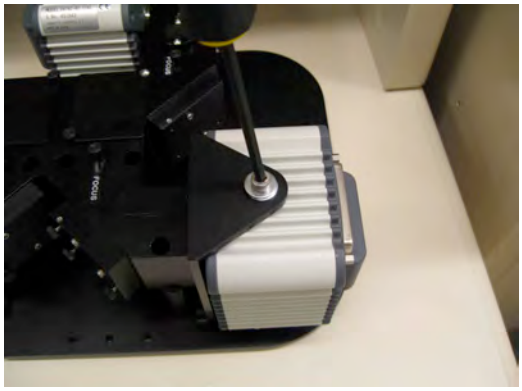
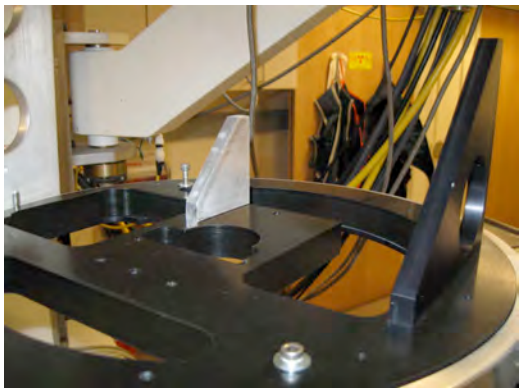
A9 Motor Mount to Lens Tube
A1-5 Temp Sensor Board
A8 Light Source Housing Assembly
A10 Appendix A Head Breakout Panel Assembly
Other Assemblies Will be completed in the course of this assembly
A7 Head DAQ Breakout Connection
A11 Motor Control Board wiring

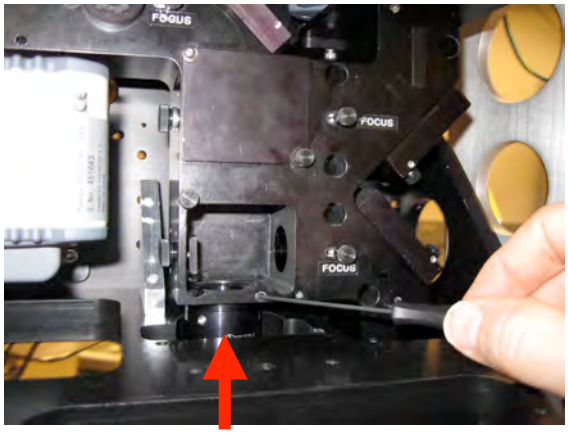
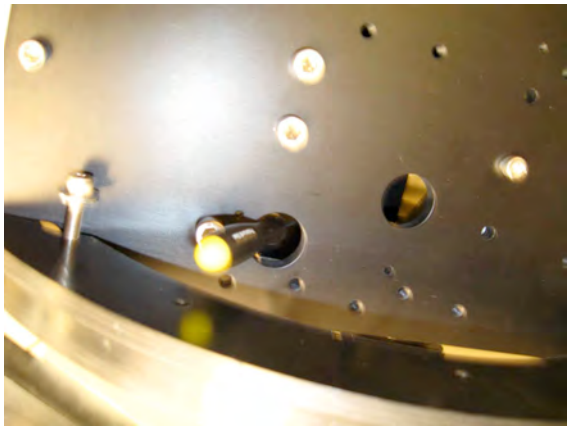
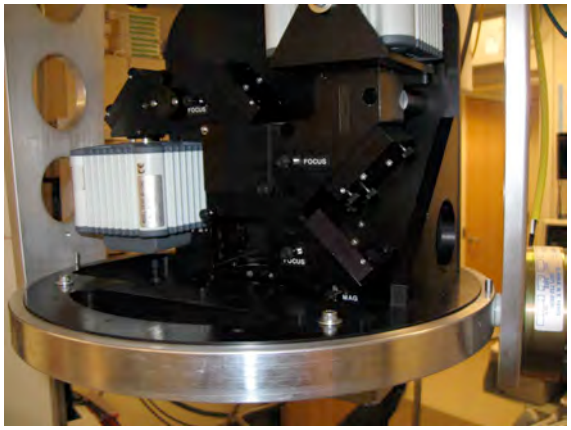
6. PROCEDURES

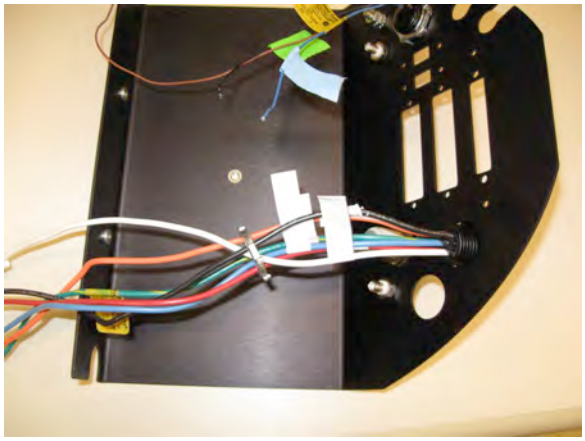
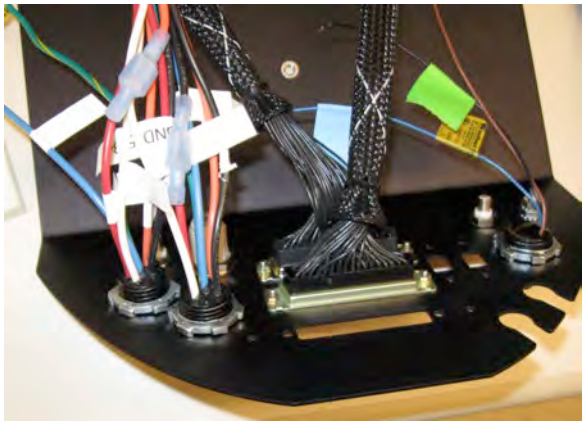
Step 1. Backplate and Optical Assembly	
A. Attach optical standoffs to the backplate using 1/4 inch -20 x 0.5 inch socket head cap screws (SHCS)	
B. Attach the color camera bracket to the camera. The 8-32 SHCS should be loose, and the firewire connections should be facing the bracket mount.	

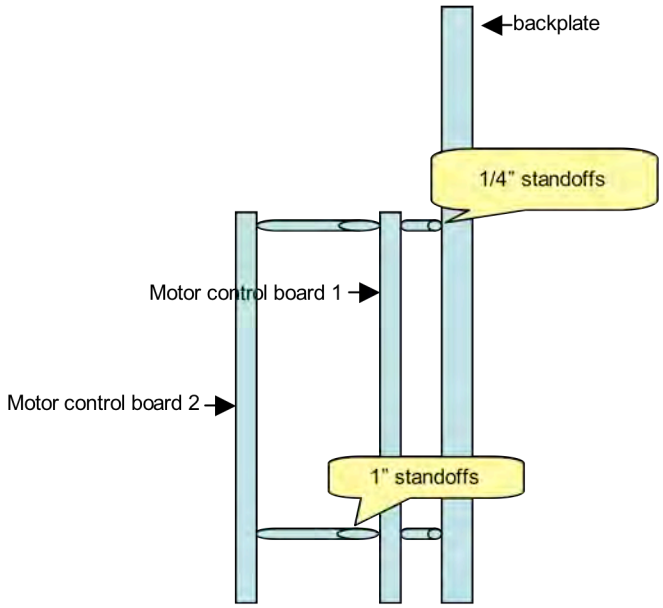
C. Attach the color camera to the backplate using 10-32 SHCS. These should remain loose.	
D. Assemble the NIR Camera 2 mount, and attach it to one of the NIR cameras. Again, ensure the screws are a little loose to allow for adjustments.	
E. Attach Camera 2 to the optical bench and secure the C-mount with only the two outside set screws.	

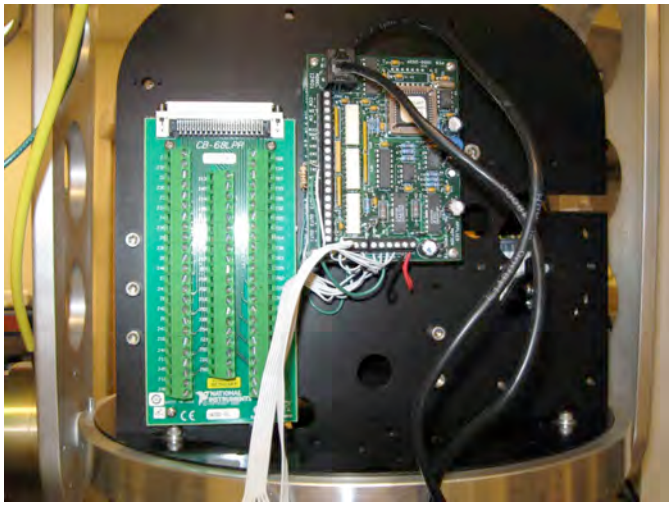
F. Attach the optical assembly to the backplate standoffs, Do this by first carefully sliding the color camera opening over the color camera. Fasten the optical mount to the backplate using 1/4 -20 x 0.5 SHCS screws.	
G. Secure the color camera to the optical assembly by tightening the two C-mount screws indicated, Hold the camera to the optical assembly firmly while tightening the screws.	
H. Place NIR Camera 1 mounting assembly on the optical assembly as shown. Note the direction of the single screw securing the two pieces. This screw should be screwed in loosely. Attach the mount to the back plate.	

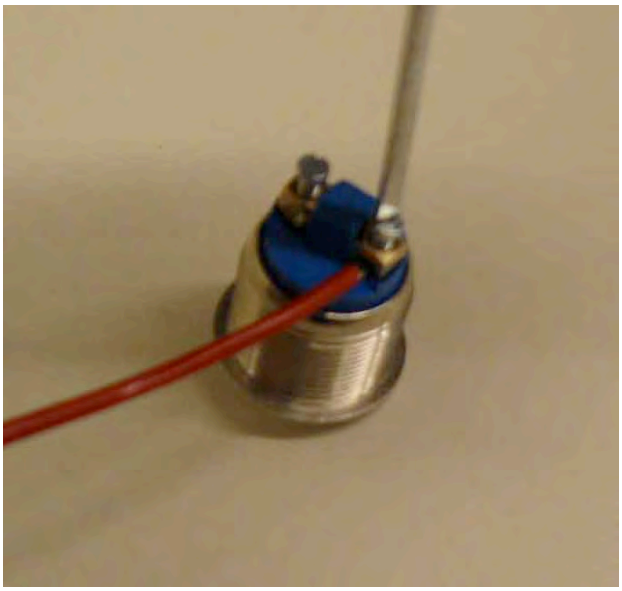
I. Secure NIR Camera 1 to the optical assembly by tightening the two C-mount screws indicated. Hold the camera to the optical assembly firmly while tightening the screws.	
J. Secure Camera 1 to the mount using a 1/4-20 x 3/8 inch SHCS and 2 x 1/4-20 washers. This screw should remain loose until final alignment.	
K. Attach the backplate brackets to the lazy susan.	

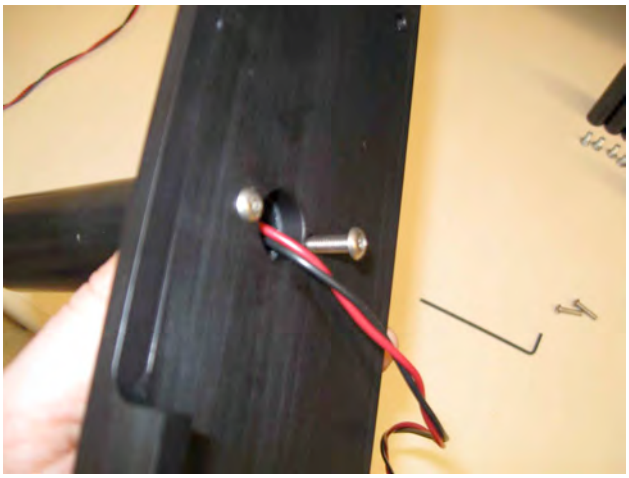
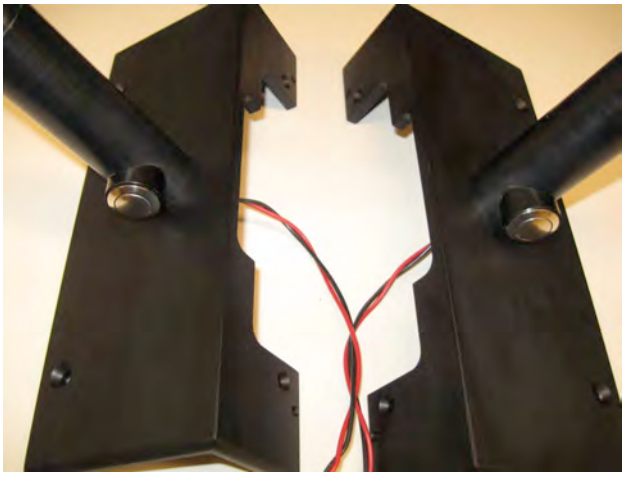
L. Attach the Focus/Zoom Assembly (SOP A9 Motor Mount to Lens Tube). Assistance may be necessary to put the optical assembly into the head, and to also slightly tilt the assembly back so that the Focus/Zoom C-mount screws are accessible. Insert the Focus/Zoom assembly from underneath the lazy susan and secure it by tightening all 3 C-mount screws. Note that the filter cube shield needs to be removed to gain access to the front C-mount screw.	 Zoom assembly insertion direction.
M. Access to the third C-mount screw for the Zoom assembly is made through the back plate. Note the ball driver is at an angle.	
N. The backplate can be attached to the backplate brackets using 10-32x 1/2 inch SHCS; 3 are needed per bracket.	

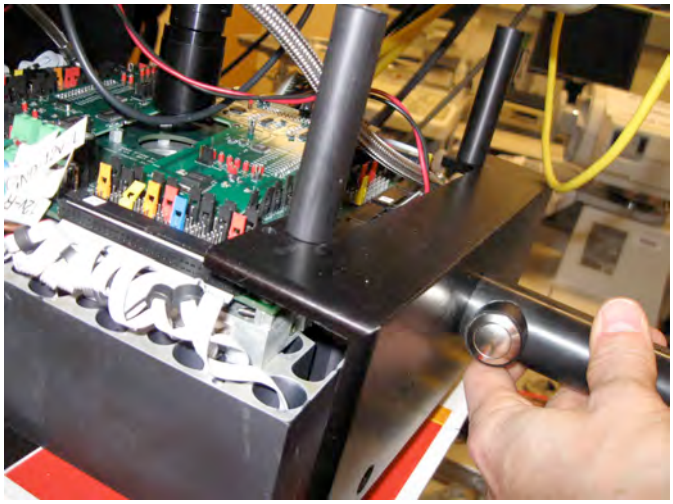
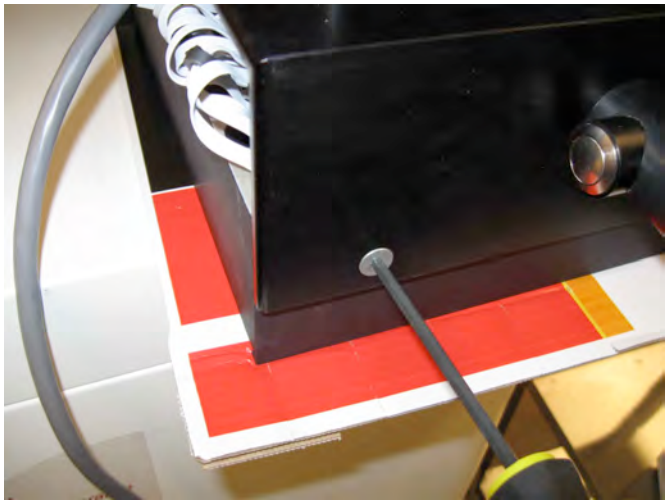
Step 2. Head Breakout Panel Assembly	
NOTE: Parts for this assembly are listed in A10 Appendix A	
A. Install the RF connectors, fiber optic feedthrough, brake connector, and ground stud, in the places shown.	
B. Insert the DC power cable assembly into the hole, feed the lock nut over the wires, and secure the connector to the panel. The connector shown is DC power number 1 (12R, 12L, 12). Repeat for DC power cable number 2 in the other hole. Install the 2x3 Molex power connectors (SOP A14 DC Power Delivery) to the terminated ends of the panel mounted power cables.	
C. Install the female ends of both camera cables into the positions shown.	

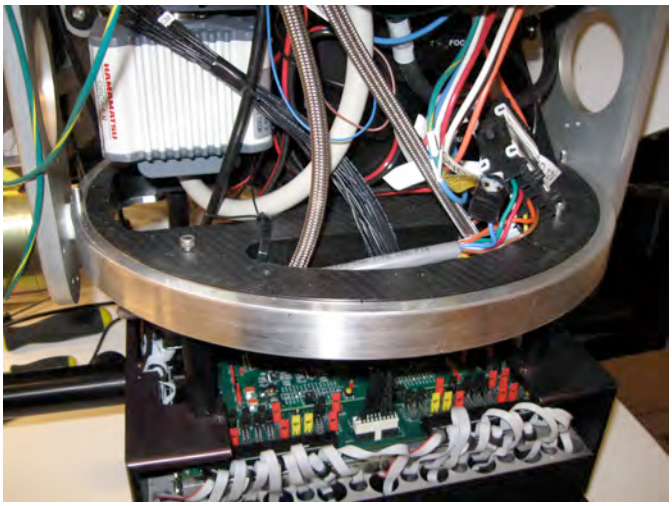
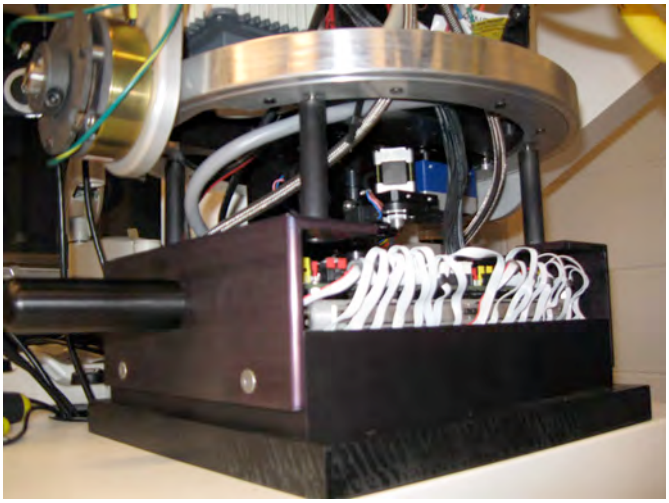
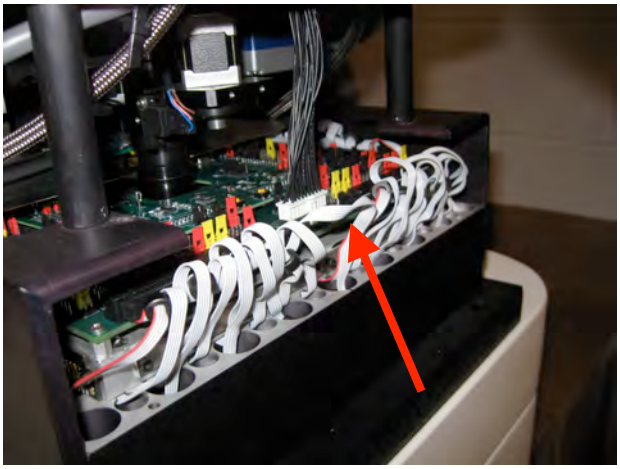
D. Install the firewire connector into the position indicated. The final DB position is filled by the DAQ cable.	
Step 3. DAQ and Motor Board Mounting	
A. Mount the DAQ breakout board on the reverse side of the backplate to the optics. The position and orientation are shown at right. Also mount the motor control boards according to the diagrams. Orientation: Receptacle for phone plug should be on TOP.	

B. To left of motor control boards are four more holes for the low voltage breakout panel. Take two (2), 1/4 inch standoffs and put together, and each hole gets a combined standoff (roughly 1/2 inch). Mount panel with Philips head 440 screws to secure. Orientation: Receptacle that receives the plug coming in to it should be on TOP.	
C. Once the panel is assembled and secured, plug in phone cords from breakout panel to motor control boards.	
Step 5: DAQ Board Wiring	
Wire the Passive Board connector, the motor board phone connectors, and the temperature sensors to the DAQ breakout board according to SOP A7 Head DAQ Board Wiring.	
Step 6.	
Mount head breakout panel to the backplate using two 10-32 x 1/2 SHCS	

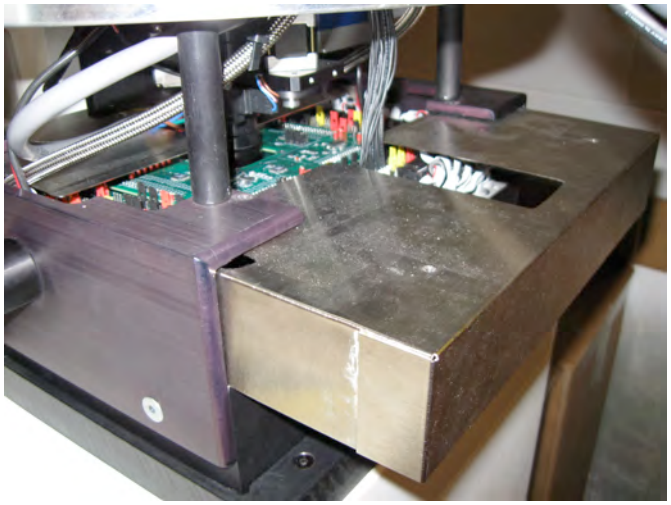
Step 7: Brake Handle and Light Source Mount Assembly	
A. Cut 24 inches of both red and black 18AWG wires. Strip about 1/8 inch off both ends. Insert the ends into the brake switch and secure the wires with the screw terminals.	
B. Feed both wires through the brake handle.	

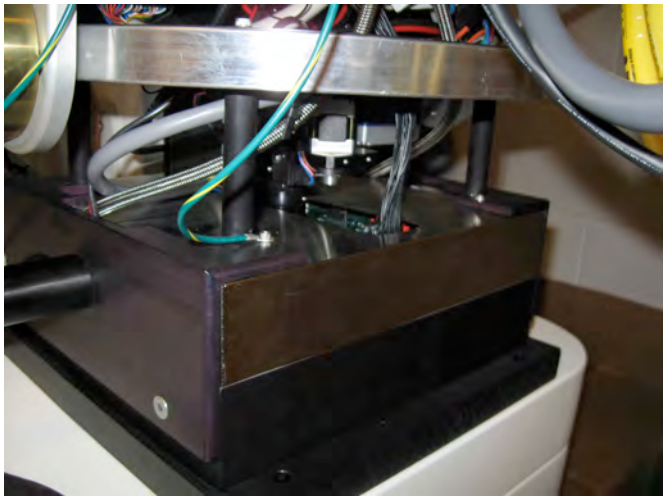
C. Feed the wires through the light source mount and attach the handle to the mount using two (2) 1-32 x 1/2 button head cap screws.	
D. Repeat for the other brake/light source mount assembly.	
E. Attach the light source mount standoffs to the light source mount using 10-32 x 3/4 flat head cap screws (FHCS)	

Step 8. Attach Light Source to Head	
A. Before attaching anything else to the light source, connect the cooling cables to the cooling plate.	
B. Carefully place the light source mount assembly along one side of the light source, (in orientation shown) making sure that none of the cables on the light source are pinched.	
C. Attach the light source mount to the light source using two 1/4-20 x 1/2 FHCS.	
D. Repeat for the other side.	

E. Find a place beneath the head to put the light source assembly. Place four 10-32 x 1.25 inch SHCS and washers in the light source support holes located on the lazy susan. Lower head to that the bolts line up with the right source support standoffs.	 
F. Complete the passive board connection.	

G. Install the RF shield.





Step 9. 34V Connections

A. The DC 30V connections need to be completed with the Head Breakout panel installed. A Molex 2x3 male-female pair will be used to complete the connections.

Part	Vendor	number	Qty.
3x2 power conn. Recept.	Molex	43914-1101	1
3x2 power conn. plug	Molex	42815-0042	1
3x2 TPA Clip	Molex	43980-1001	2
Female crimp terminals,14-16AWG	Molex	42815-0042	3
Male crimp terminals,14-16AWG	Molex	42817-0042	3

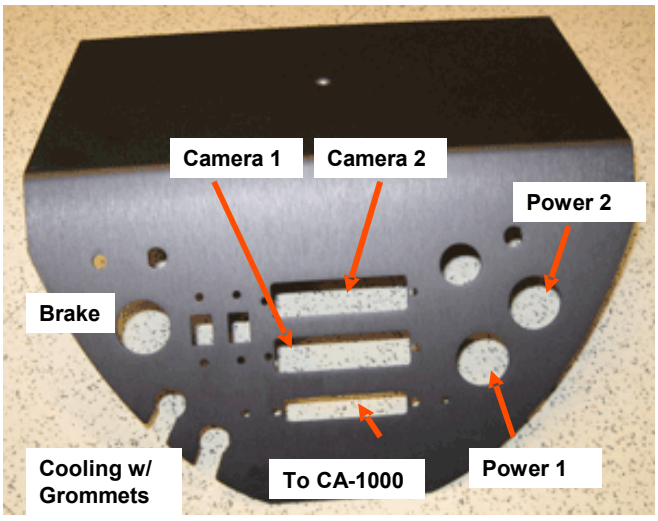
B. The connections will be made according to the table below.

Connector	Molex Connector Pin#	Desc.	Wire Color
Receptacle	1	34V + in	Green/Yellow
Receptacle	4	34V GND in	Blue
Plug	1	2 wires to brake switch	Red
Plug	1	1 wire to Motor control	Red
Plug	3	2 wires from brake switch	Black
Plug	3	1 wire to brake connector	Blue
Plug	4	1 wire from brake connector	Black
Plug	4	1 wire from Motor control	Black

Note: Multiple wires will be crimped into the terminals on the plug.

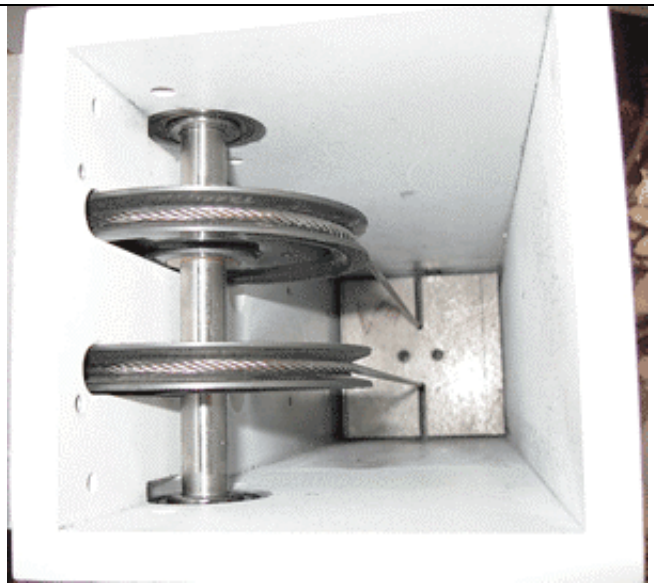
Step 10. Final Connections

With the cable harness in, complete the connections to the head as pictured.



Unassembled

	 Assembled
Step 11, Head Cover	
Once system testing is complete, the head cover can be put on.	
Step 12. Counterweight Arm	
A. Use steel “shot” provided by Gordon Row to fill the container located inside the mast. The weight of the shot will counterweight the arm and head. Stand up near the system to see down into the mast.	
B. Use the long funnel provided by Yankee Modern to fill the container, and place the end of the tube into the hole in the central mast container. (A flashlight may be necessary to see the hole if the lighting is not adequate) Slowly fill the container with steel shot using the funnel.	
C. NOTE: It is very important that the shot does not spill into the mast or around the pulley system. The funnel will need to be refilled multiple times because the container will hold quite a bit of shot.	

Occasionally agitate the shot in the container with the end of the funnel so that they shot completely fills the container. Make sure the shot does not overflow into the mast when the level of shot reaches close to the top of the container. Check with a flashlight to ensure that the container is completely full.	
D. Once the container is full, take 10 weight plates (provided by Gordon Row), and stack them on top. Weights have cut outs for pulley wires. Weights need to be dropped in vertically between pulleys and then flipped horizontally once in mast hollow. The will only lay flat one way when they are flipped so they cannot be put in incorrectly.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP A10 for Full Head Assembly	04/21/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A10 Appendix A
Head Breakout Panel Assembly

Version 0 (10/01/2011)

Approval Signatures

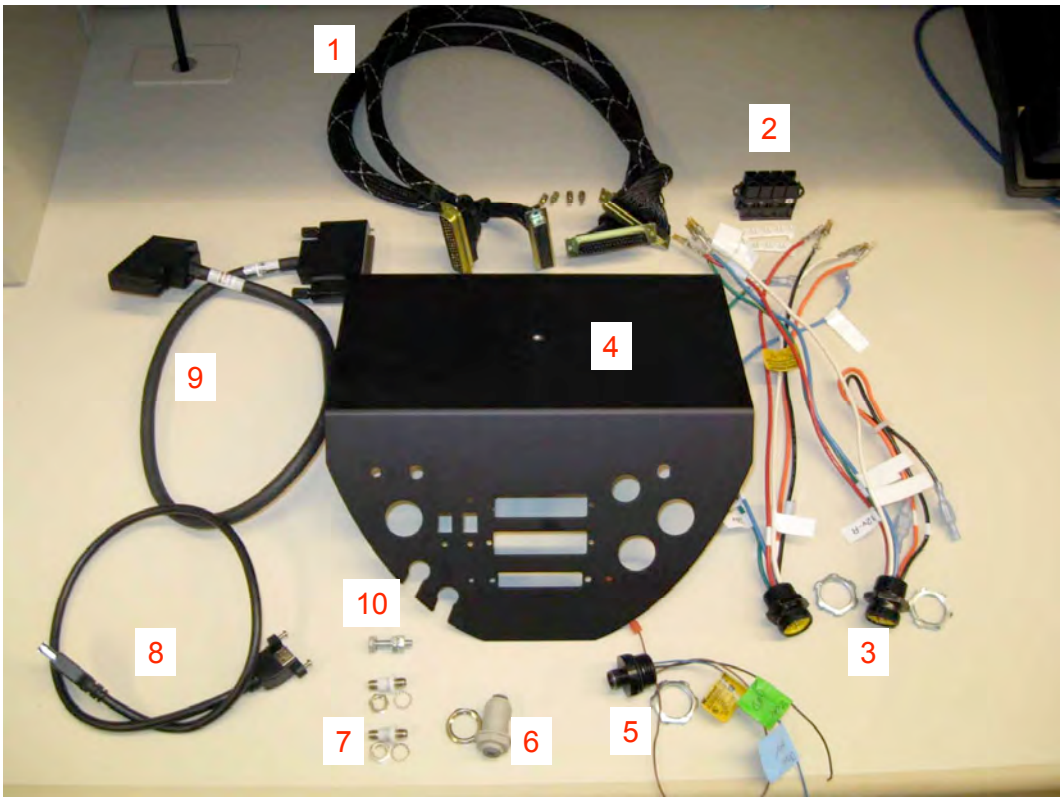
Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A10 Full Head Assembly	None	None

Head Breakout Panel Assembly

The parts in the picture below are described in the table.

Number	Part Description	Vendor	Part Number
1	NIR camera cables	Orca	Comes with NIR camera
2	2x4 pin power connector w/ locks	Molex	43938-2102
3	DC power cable assemblies (SOP A14 DC power delivery)		
4	Head Breakout Panel	Yankee Modern	
5	Brake Connector		
6	Fiber Optic Feed through		
7	RF connectors		
8	Color Camera firewire cable	Datapro	1398-02C
9	DAQ SCSI connector cable 2ft.	Dynamic Engineering	HDEcabl 68-2 M/F
10	Nuts and bolts		



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A10 Appendix A Head Breakout Panel Assembly for SOP A10 Full Head Assembly	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A11
Motor Control Board Wiring

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Alan Stockdale	04/22/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A8 Low Voltage Breakout Panel	None	None

1. PURPOSE

The purpose of this document is to outline the procedures for the Motor Control Board wiring used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel wiring the Motor Control Board for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

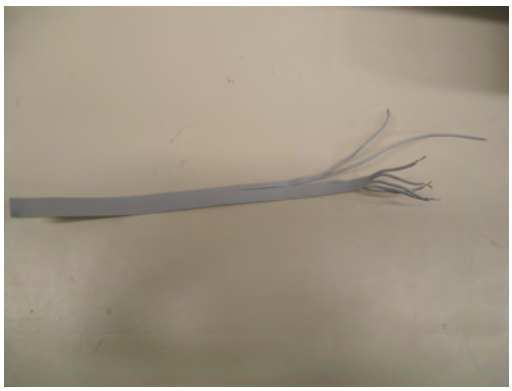
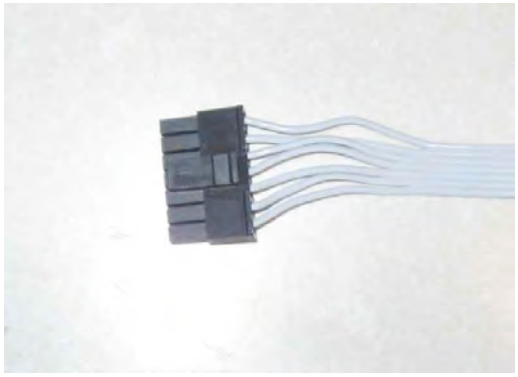
5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

Part Description	Manufacturer	Part#	Qty.
Strand of ribbon cable with 7 conductors	Alpha Cable	3801/60-100	10 inches
7 pin connector, receptacle	Molex	0436450700	1
7 pin connector, plug	Molex	0436400700	1
Crimp pin, F	Molex	0430300001	7
Crimp pin, M	Molex	0430310001	7

Wire stripper/cutter
Screwdriver
Needle nose pliers

6. PROCEDURES

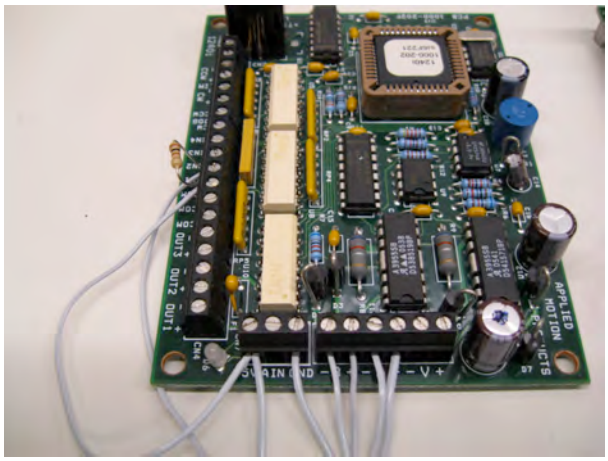
Steps	
A. Two (2) motor control boards like the one pictured are needed.	
B. Cut off a 10-inch piece of the 60-conductor ribbon cable. Separate into two 7-conductor pieces; discard the rest.	
C. On one end use the Male crimp terminals to attach the 7-pin Molex plug connector.	

D. Looking at the labels on the motor control boards, the 7 wires should be connected as follows:

Molex #	Label on board
1	B-
2	B+
3	A-
4	A+
5	GND
6	In1
7	+5V

Also, connect a resistor from IN1 to the COM terminal right next to it.

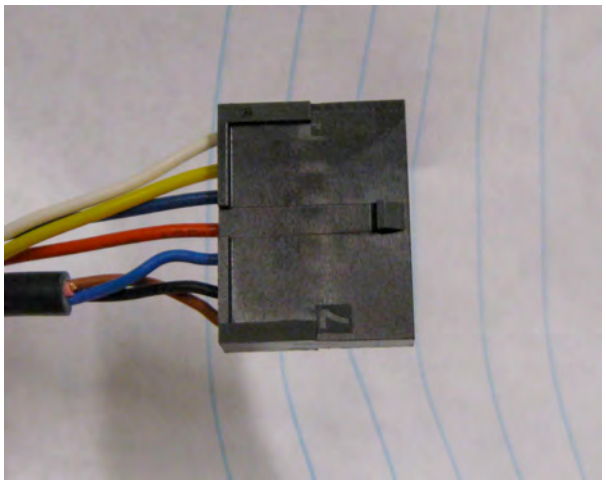
Connect a separate 4 inch wire from the COM terminal to +5V.



E. The wires from the motors need to be inserted into Molex connectors as well. Use the plug connector, and the Male crimp pins.

The wiring should be as follows:
(the first 4 come from the cube-shaped area; the other 3 are on the side of the motors).

Molex #	Label on board
1	White
2	Yellow
3	Blue
4	Red
5	Lt. Black
6	Black
Brown	



F. Two phone plugs connect the motor control boards to the DAQ I/O breakout board. Cut them to be about 9 inches long from the tip of the connector. Expose the four (4) internal conductors on the cut end and strip about 1/8 inch of the insulation from each conductor. These will be wired into the DAQ low-voltage breakout panel according to SOP A7.

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A11 Motor Control Board Wiring	04/22/2009	Alan Stockdale
V 1.0	Modified Record	Edited	04/25/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A12
Isolation Transformer

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Alan Stockdale	04/23/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	None

1. PURPOSE

The purpose of this document is to outline the procedures assembling the Isolation Transformer used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the Isolation Transformer for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

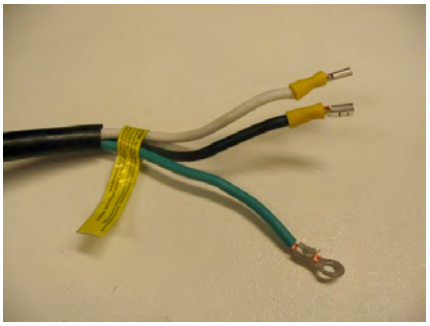
The following materials will be needed for the completion of this SOP.

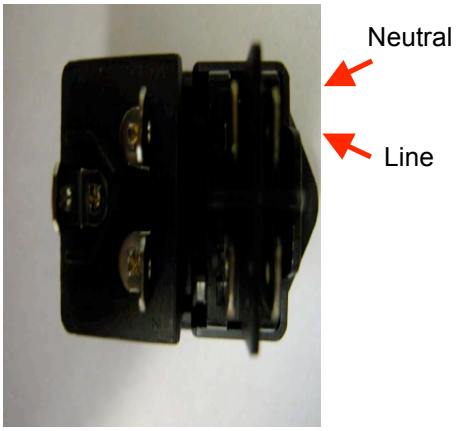
Name	Qty.	Vendor	Part #	Picture
Isolation Transformer 1800W, 6NEMA 5-15/20RHG	1	Tripp Lite	IS1800HG	
Disconnects – F Vinyl-Insulated Barrel • Rated at 600 V Max • Temp rating: 167 °F (75 °C).	2	Gardner-Bender	20-145F	
Bare Ring Terminal #12 to #10 AWG, 1/4 Stud	1			
Craftsman Professional Crimper/Stripper/Cutter				

6. PROCEDURES

Steps	
A. Remove the screws.	
B. Loosen the additional screws.	
C. Remove the plug and cover.	
D. The wires coming from the plug are soldered. Using a Crimper/Stripper/Cutter tool, cut the soldered part, and un-strap about 1/4 inches of the three lines (white-neutral; black-line; green-ground).	

E. Insert line and neutral wires to two Disconnect -F connectors. Use the Crimper/Stripper/Cutter tool to crimp them firmly.

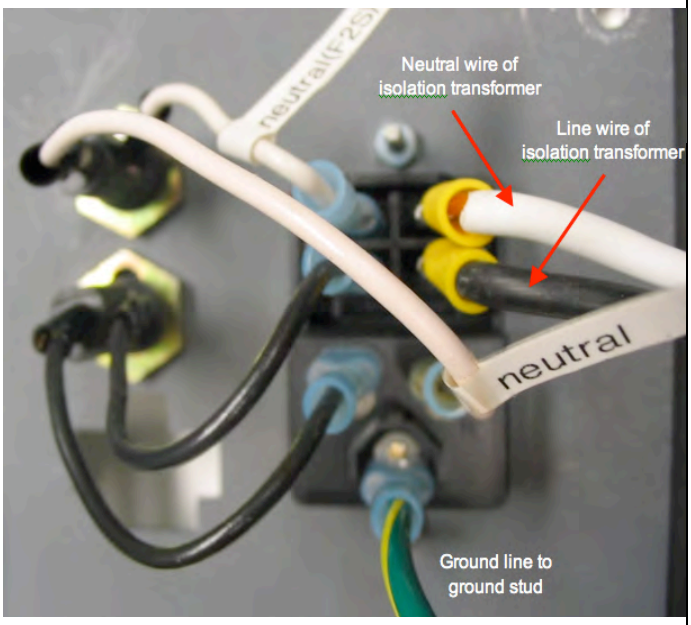




F. Insert ground wire to 1 bare ring terminal. Use the Crimper/Stripper/ Cutter tool to crimp it firmly.

G. Shown above are the assembled wires (Step 5 - top) and the unassembled PEM (Step 5 - bottom).

Connect the appropriate isolation transformer wires to corresponding connectors on the PEM. Shown below is the assembled isolation transformer wires (neutral-white and live-black) connected to the power entry module.



H. The ground line of the isolation transformer and the ground line of

the power entry module will both be connected to the ground stud that is close to the cart entry module inside the cart.	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Isolation Transformer.	04/23/2009	Alan Stockdale
V 1.0	Modified Record	Edited.	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A13
Cart Entry Panel

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara Clough	04/22/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A19 CA-1000	None	A13 Appendix A
		A13 Appendix B
		A13 Appendix C

1. PURPOSE

The purpose of this document is to outline the procedures assembling the Cart Entry Panel used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the Cart Entry Panel for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for the completion of this SOP.

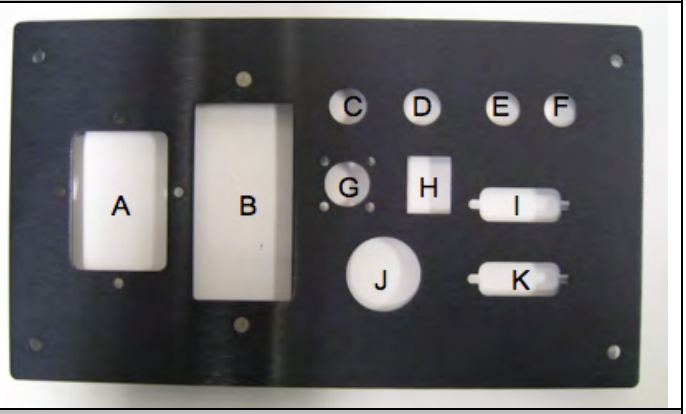
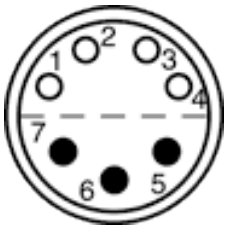
Name	Qty.	Vendor	Part #	Picture
Power Entry	1	Schurter	EC11.0031.001	
Fuseholder	2	Little Fuse	342014	
FUSE 20A 250V T-LAG CRM MDA	2	Cooper / Bussmann	BK/MDA-20-R	

Name	Qty.	Vendor	Part #	Picture
Avikrimp™ Fully Insulated Quick Disconnect, Female, for 14-16 AWG Wire, Box	5	Molex	0190020037	
Category 6 Shielded RJ45 (8x8) Keystone Feed-thru Coupler	1	L-Com	TDG1026KS-C6	
DVI Bulkhead Adapter Female/Female (2)	1	L-Com	DMB605FF	
4-40 Jack Screw Kit, .250 inch Thread, .232 inch Screwlock, Pkg/50	4	L-Com	SDG250	
Hospital Grade Ground Jack	1	Isotrol	HGJ-1R	
AC receptacle	1	Leviton	16262-HGW	
Cord with 3-prong NEMA 5-15 plug	2	McMaster Carr	70355K35	

Name	Qty.	Vendor	Part #	Picture
Heatshrink tubing	1	Alpha Wire Company	F221B3/64 BK205	
Cord Retainer Kit		Schurter	4700.0012	
12 conductor cable 24 AWG strand (1 ft)	1	Alpha Wire Company	1219/12C SL005	
LEMO connector	1	LEMO	EBD-2S.307.CLL	
Phone Jack, Audio, Stereo, 6 mm	2	Switchcraft	152B	
DB15 male/female connector	1	Norcomp	171-015-203L031	

Required Tools
Craftsman Professional Crimper/Stripper/Cutter
Soldering Iron
Solder
Screwdrivers
Heat Gun for Shrink Wrap

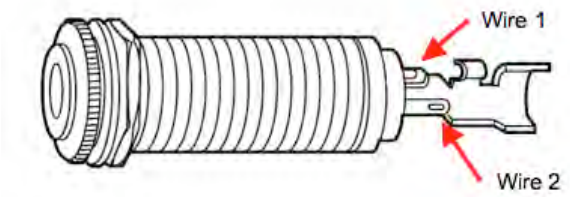
Cart Entry Panel Assembly

Step 1. Labeling the Panel	
Cart Entry Panel Layout as found in A13 Appendix A	
Step 2. Footswitch LEMO Connector and Phone Jacks	
A. Insert LEMO Connector into the cart entry panel (Location G); use 4-40 screws and nuts to keep it in place.	
B. Insert two phone jacks into the panel for the ECG signal (Location E) and Respiratory signal (Location F). Use the two included hex nuts to secure them firmly.	
C. Cut out 1 foot of 12-conductor wire. Strip six inches of the grey casing off one end.	
D. Solder seven of the twelve wires from the stripped end into the LEMO connector as shown in the figure.	 Rear view of LEMO connector

Color	LEMO pin #
Red	1
Blue	2
Orange	3
Green	4
Beige	5
Pink	6
Grey	7

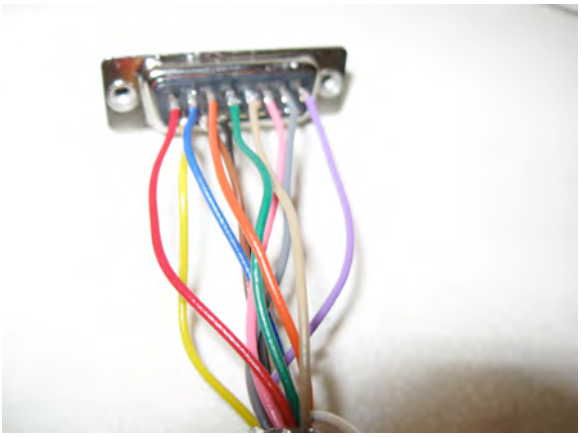
E. Solder four of the remaining wires to the phone jacks.

Signal	Wire
ECG	Wire 1 – Yellow
	Wire 2 – Purple
Respiratory	Wire 1 – Black
	Wire 2 – Brown

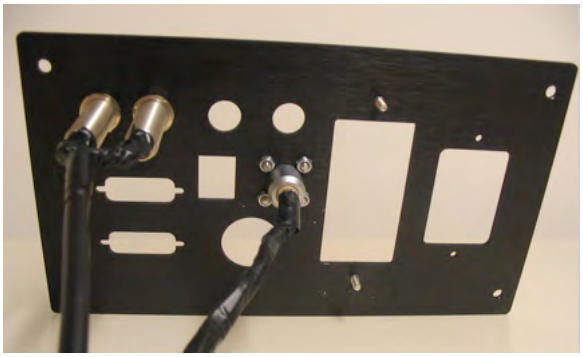


F. Solder the eleven wires into the side of the DB-15 connector shown in the top image. The bottom image is an example of completed soldering.

DB15 Pin #	Wire Color
1	Red
2	Blue
3	Orange
4	Green
5	Beige
6	Pink
7	Grey
8	Purple
9	Yellow
10	Brown
11	Black

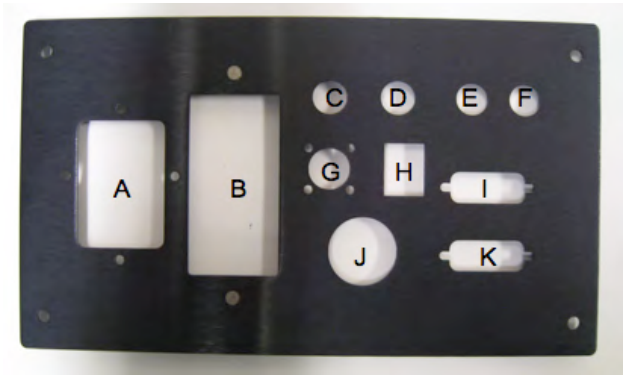


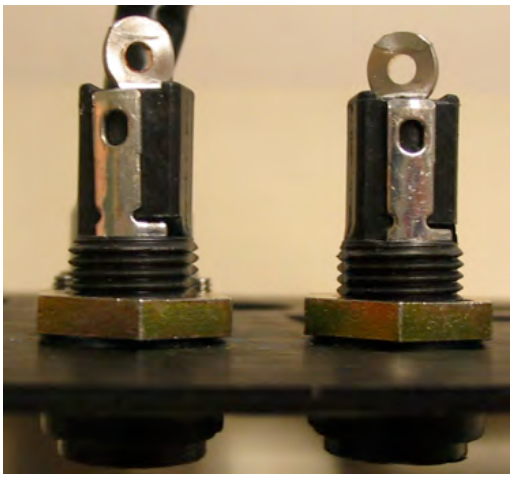
G. Use heatshrink tubing to cover all the exposed wires.

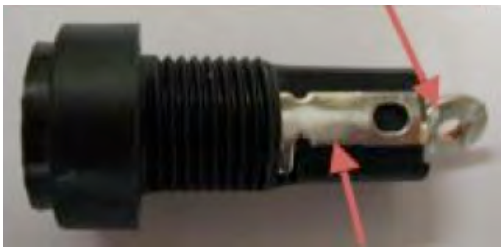


H. Refer to A13 Appendix A for Footswitch & Gating wiring diagram.

Power Entry Module and Fuse Holders

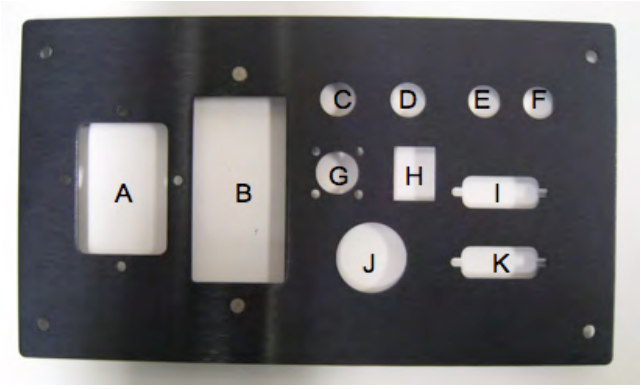
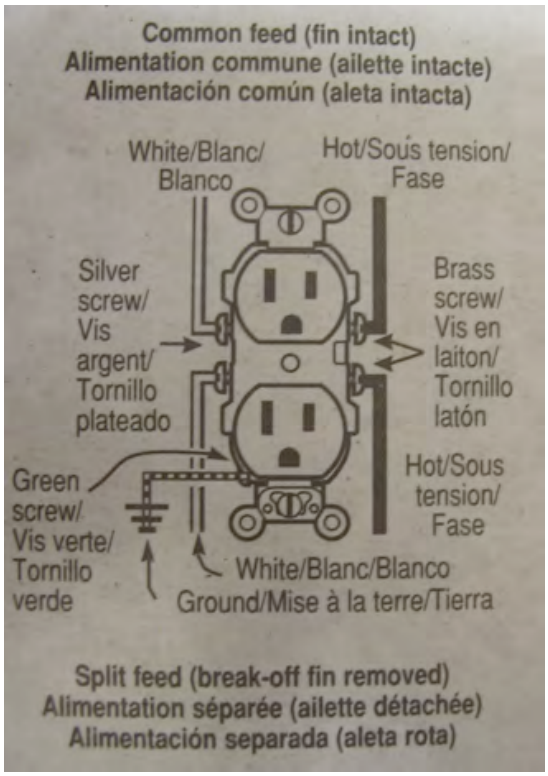
A. Refer to A13 Appendix B for wiring diagram of power entry module to fuses and isolation transformer.	
B. Insert the power entry module in the left most slot (Location A).	
C. Use two 4-40 screws and nuts above and below the power entry module to hold it in place. Insert the spacers into the two holes to the left and right sides of the power entry module, using the washers and nuts to hold them in the back. Ensure that the holes in the spacers are horizontal.	

D. Insert the retaining clip into the two holes in the spacers.	
E. To fasten the fuseholder to the entry panel, insert the fuseholder through the hole from the front. From the back, use the gold-colored hexagonal nut to fasten it.	
F. Cut five 9-inch wires from the 8-conductor, 16 AWG cable (2 white, 2 black, 1 green). Place wires in the female connector and crimp the middle portion as shown.	

G. The four black and white wires need to be soldered to the two fuses; specifically, the two metal rings as shown.	
H. Before soldering the wires, put heatshrink tubing on the wire that will be sued to cover the solder. This is not necessary if electrical tape is being used instead of heatshrink tubing.	
I. The wires are placed as shown in the picture and soldered in that position. One wire goes in the ring at the side of the fuseholder, while the other goes in the ring at the side of the fuse.	
J. After soldering, pull the heatshrink tubing over or wrap electrical tape around the soldered part. Pictured is how the fuse should look after soldering.	

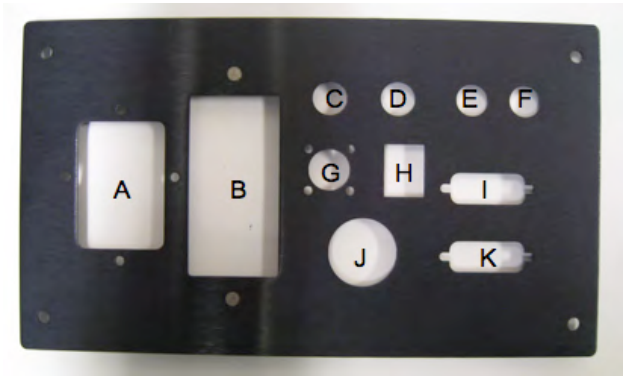
K. At the end, two sets of assembled fuse holder and wires as shown in the figure should be prepared; one with black for Line wire connections and one with white for Neutral wire connections. Label each wire properly.	
L. The head of the fuse contains two pieces; one end of the fuse fits into the cap. Together, they are then fit into the front end of the part that was soldered previously.	
M. Connect the free end of the 9-inch cut green wire to a ring crimp.	
N Connect the five wires to the back of the Power Entry Module; the two wires at the top of the wire are coming from the side of the fuseholder, while the other two just above the green wire come from the back. The other end of the green wire is not yet connected by anything (See A13 Appendix C Power Entry Wiring Diagram)..	

Assemble AC Receptacle

A. The satellite monitor is powered through the AC receptacle (location B). The receptacle itself is connected to the power strips of the cart through the 6-foot cord with 3-prong NEMA 5-15 plug.	
B. Cut the 6-ft cable to 4 feet. Strip the casing 5 inches, and strip the wires 0.5 inches. The diagram for the AC receptacle is shown to the right.	

C. Insert the proper holes and turn screws until tight. Hot = black wire = brass screw Neutral = white wire = silver screw Ground = green wire = green screw	
D. Insert the AC receptacle into its place. Some force may be required to fit the AC receptacle over the studs into the cart entry panel. Use two (2) 4-40 nuts to firmly secure the receptacle.	

DVI Connectors

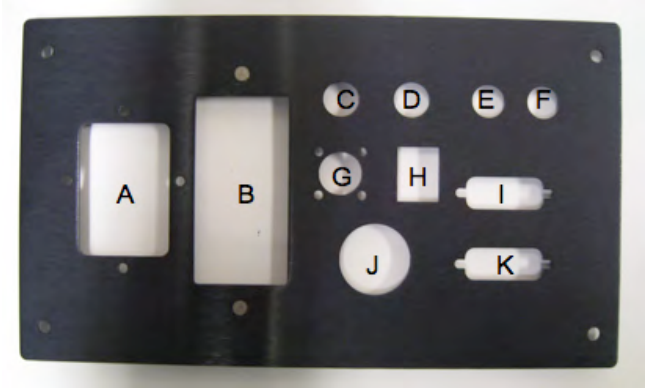
A. The satellite monitor gets its signal from the two DVI connectors on the cart entry panel. The top connector is the signal for the Control monitor. The bottom connector is the signal for the Camera monitor, which obtains the images the surgeon needs to see. Insert the two DVI connectors: Control monitor (Location I) and Camera monitor (Location K)	
Note: The screws supplied with the connectors are short compared to the panel thickness. Hence one should use the 4-40 Jack Screw Kit to mount the DVI connectors.	
B. Remove the two screws, one on each side of the DVI connectors.	
C. Use the two screws from the 4-40 Jack Screw Kit from L-Com to fasten the DVI connectors to their proper place on the cart entry panel.	

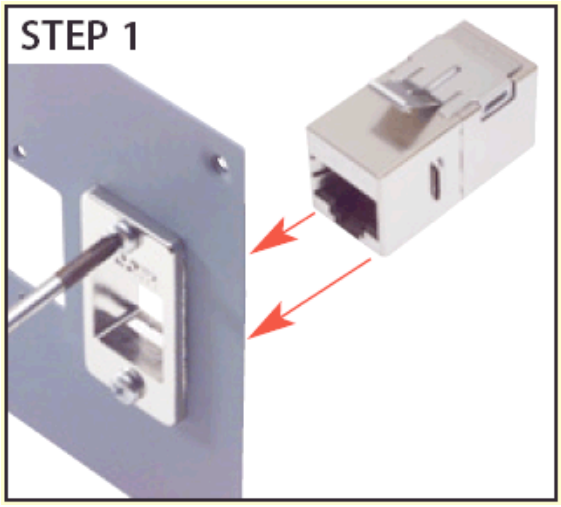
RJ45 Feed-thru Coupler

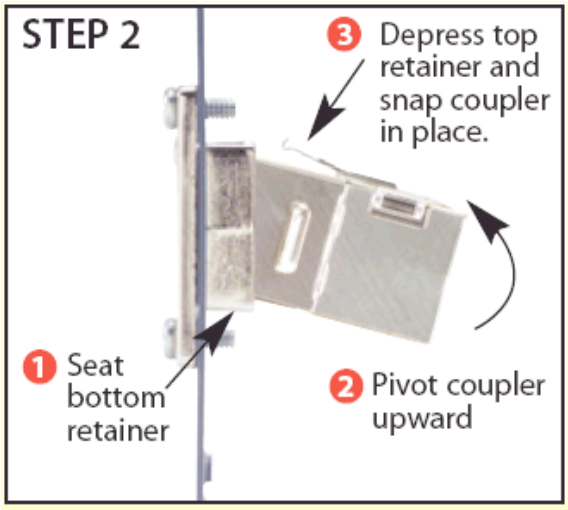
The RJ45 Feed-thru Coupler allows the computer to be connected to the Internet.

A. Follow the steps in the figure to the right and insert the Feed-thru Coupler (location H).

B. Align the coupler in proper orientation to the opening. Seat bottom retainer and pivot coupler upward while depressing upper retainer.





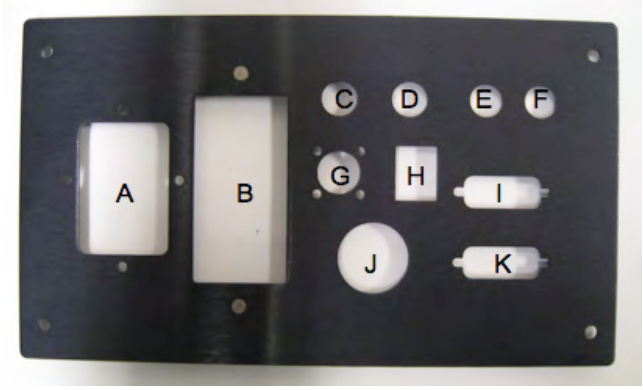


RJ45 Installation

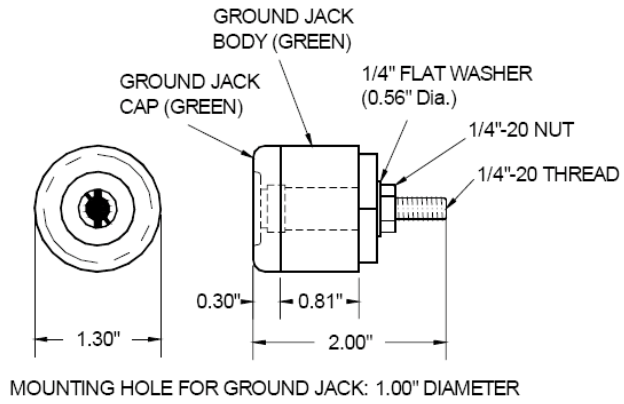
Ground Jack

The ground jack allows clinical engineering to test the grounding of the cart.

A. Remove the ground jack cap. Insert the ground jack from behind (location J) and screw the cap on from the front.

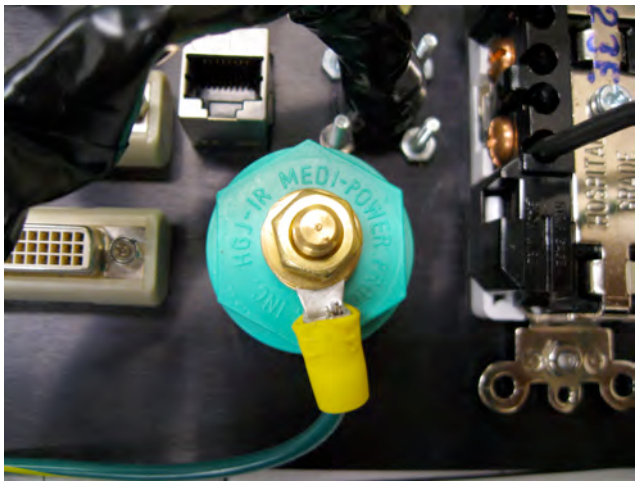


B. Cut a 10-inch wire from the green 16 AWG cable (same as before). On one end, crimp a ring terminal; on the other end, crimp a 10-12 AWG yellow ring terminal, which is big enough to fit over the stud of the jack.

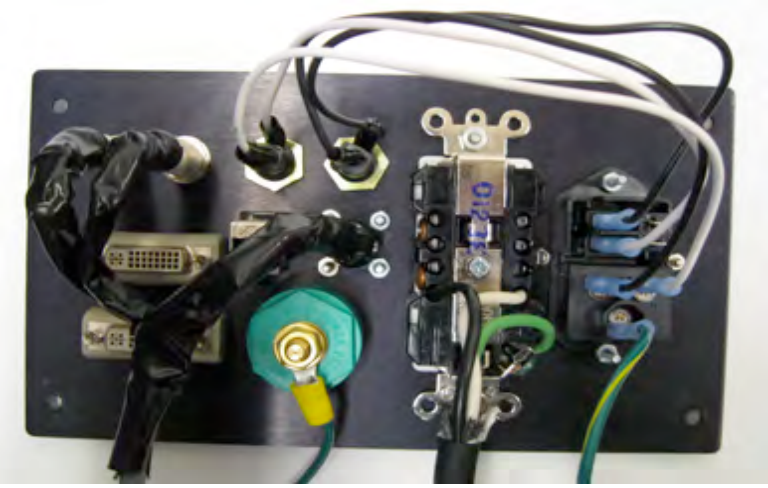


Ground jack specifications

C. The ground jack should look as pictured, taken from the back of the entry panel.



Final Product



The interior of the fully assembled cart entry panel.

The exterior of the fully assembled cart entry panel.

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for Cart Entry Panel.	04/22/2009	Barbara Clough
V 1.0	Modified Record	Edited	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A13 Appendix A
Cart Entry Panel Layout

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A13 Cart Entry Panel	None	None

Cart Entry Panel Layout

There are 11 connectors that need to be connected to the cart entry panel as follows:

A. Power entry module
B. AC receptacle for monitors
C. Fuse 20A- line
D. Fuse 20A- neutral
E. ECG signal
F. Respiratory signal
G. LEMO
H. RJ45 feed-thru coupler
I. DVI adapter – control
J. Ground jack
K. DVI adapter - cameras

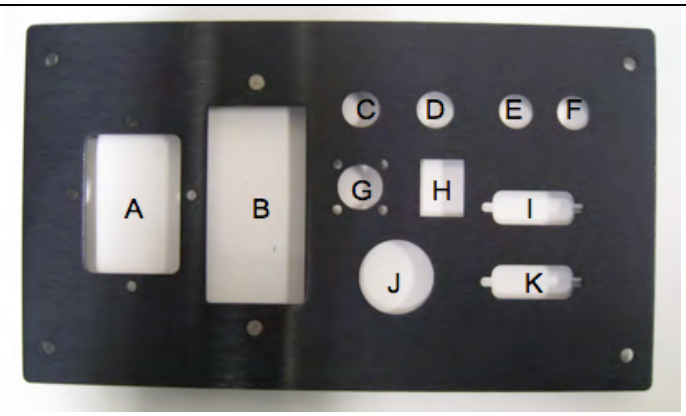


Figure 1. Cart entry panel.

a. Use label maker and print labels as shown in Figure 1 and place on the panel.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A13 Appendix A Cart Entry Panel Layout SOP A13 Cart Entry Panel	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A13 Appendix B Footswitch and Gating Wiring Diagram

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A13 Cart Entry Panel	None	None

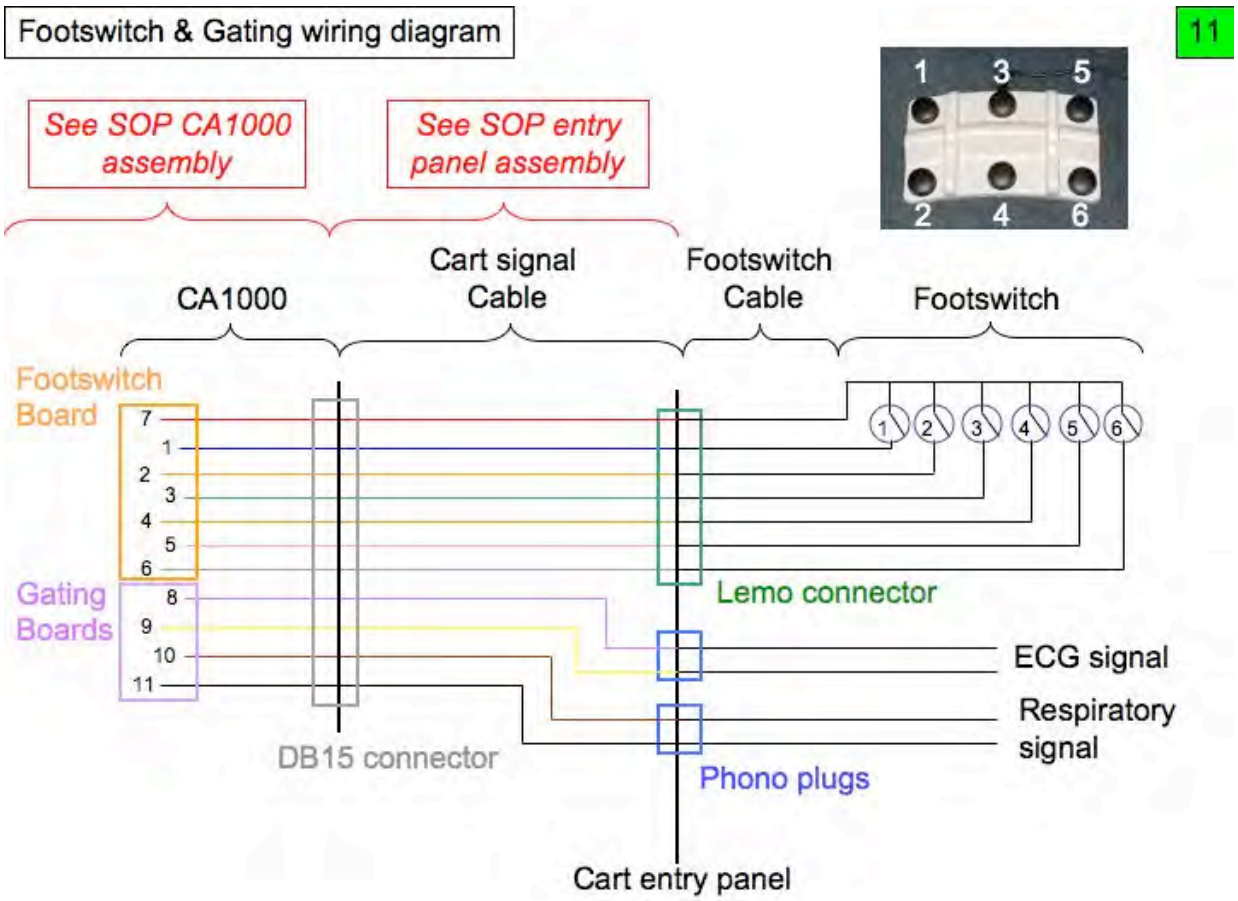


Figure 1: LEMO connector, phone plugs, and DB-15 diagram.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A13 Appendix B Footswitch and Gating Wiring Diagram for SOP A13 Cart Entry Panel	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A13 Appendix C
Power Entry Wiring Diagram

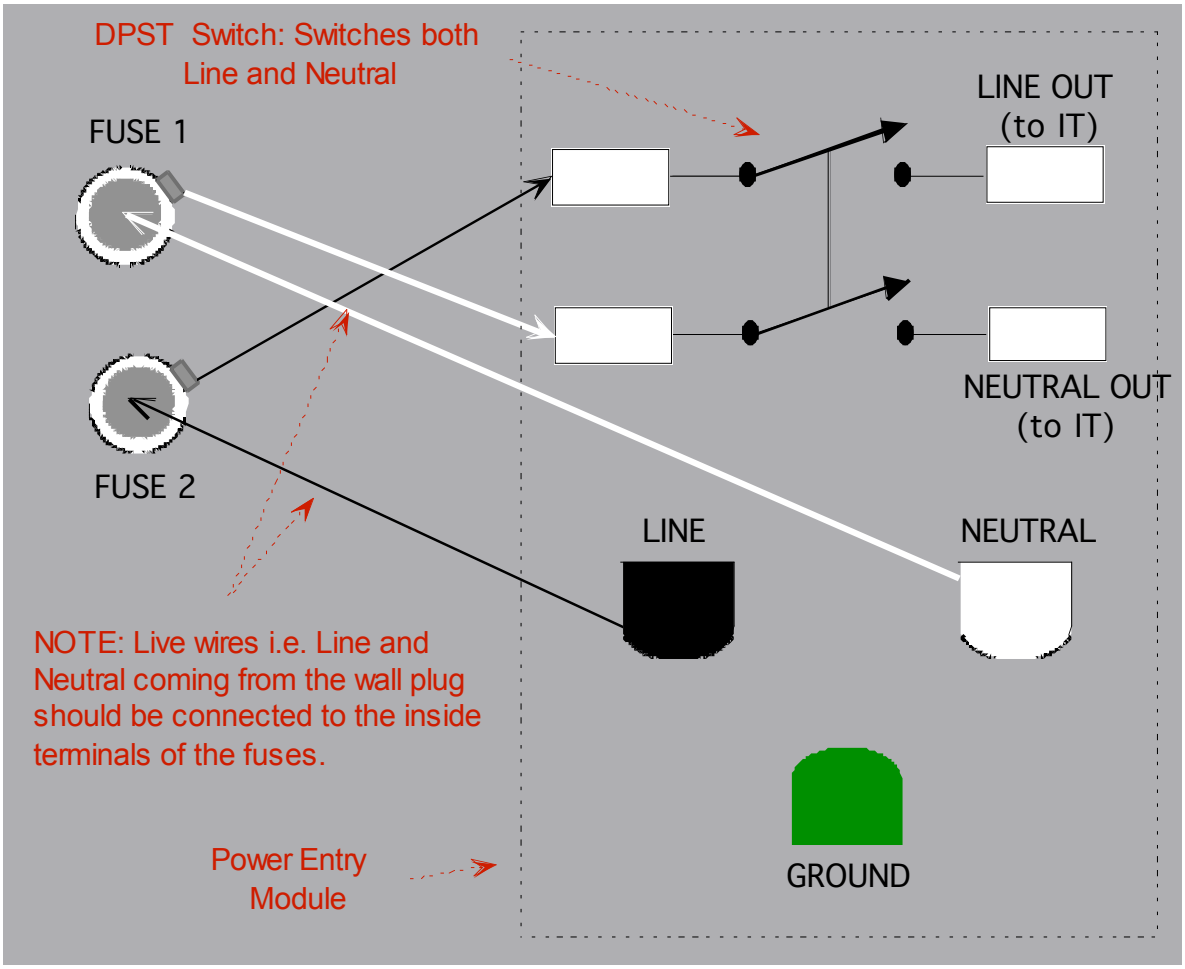
Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A13 Cart Entry Panel	None	None

Figure 1. Wiring Diagram: From power entry module to fuses and isolation transformer (T).



Note: In general, for domestic application the preferred wire color for the line is black and for neutral is white. In international applications, brown is used for line and blue is used for neutral. In both cases, ground is shown with green or green/yellow.

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A13 Appendix C Power Entry Wiring Diagram for SOP A13 Cart Entry Panel	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A14
DC Power Delivery

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Authors: Alan Stockdale Barbara Clough	04/22/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A8 Light Source Housing	None.	None.

1. PURPOSE

The purpose of this document is to outline the procedures assembling the DC Power Delivery used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the DC Power Delivery for the FLARE™ imaging system.

3. RESPONSIBILITIES

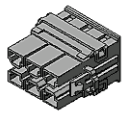
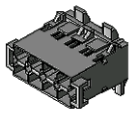
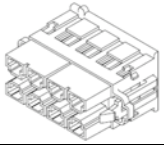
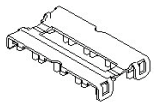
The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

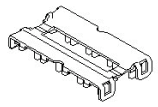
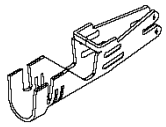
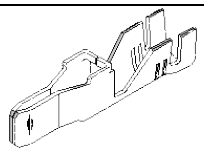
4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for the completion of this SOP.

Item	Qty.	Vendor	Part #	Picture
3x2 Molex power connector, receptacle, .393 inch pitch	2	Molex	43914-1101	
3x2 Molex power connector plug, .393 inch pitch	2	Molex	43938-2102	
4x2 Molex power connector plug, .393 inch pitch	1	Molex	43938-2102	
3x2 Molex power connector receptacle, .393 inch pitch	1	Molex	43914-1102	
3x2 TPA clip for Molex power connectors	8	Molex	43980-1001	

Item	Qty.	Vendor	Part #	Picture
4x2 TPA clip for Molex power connectors	4	Molex	43980-1002	
Female crimp terminals, 14-16AWG, Gold	12	Molex	42815-0042	
Male crimp terminals, 14-16AWG, Gold	18	Molex	42817-0042	
Insulated ring terminals (14 AWG-16AWG)	12	Radio Shack	64-3117	
Modular power supply 5V, 12V, 15V, 15V, 24V, 28-34V	1	Cosel USA	AC9-NMJHFF-00	
8 conductor cable 16 AWG strand (1 ft) 8 conductor cable 16 AWG strand (1.5 ft)	2 1	Alpha wire	5078C	
Power cables, 6 conductor, 20 ft	2	Woodhead	106000A01F200	
6 Conductor male receptacle for power cables, 12 inch wire	2	Woodhead	106000A01F120	

Required Tools
Craftsman Professional Crimper/Stripper/Cutter
Screwdriver
Needle-nose pliers
Multimeter with alligator clip leads

6. PROCEDURES

Introduction
There are 6 power modules on the Cosel DC Power Supply: 12V, 12V, 24V, 34V, 5V, 12V. For ease of use and flexibility, the main power cables will not be directly connected to the power supply. Instead, an intermediate cable will be used. One end is connected to ring terminals, which are in turn connected to the power supply, and the other end is connected to a 3x2 Molex female power connector. The main power cable will then be connected to the DC source harness through a mating 3x2 Molex male power connector.

Note: The yellow Woodhead power cables have 6-conductor male receptacles, which means that in order to transfer all 6 voltages (2 output each for positive and negative connections) to the imaging head, two sets of 6-conductor cables are needed. The breakdown is:

Cable 1: 12v (right), 12 v (left) and 24v
Cable 2: 34v, 5 v and 12v

A diagram showing pin assignments is included in step C.1.f. (below).

Step 1. Assembly – Preparation of Intermediate Cable Assembly	
A. Take one of the 1 ft 16 AWG 8 conductor cables and use the stripper tool to strip 0.5 inches of the wire on both ends.	
B. There are eight (8) conductors in this able, but only six (6) conductors will be used (colors: red, white, green, blue, orange, and black). Take a ring terminal and insert the stripped wire inside the terminal.	
C. Using the crimping tool, crimp the terminal to the wire.	
D. Repeat steps B and C for all six conductors.	

E. Using the other end of the 8-conductor cable, repeat steps B through D, but this time instead of ring terminals, use female crimp terminals.

Note: Use a label maker to print labels on both ends of the cables.

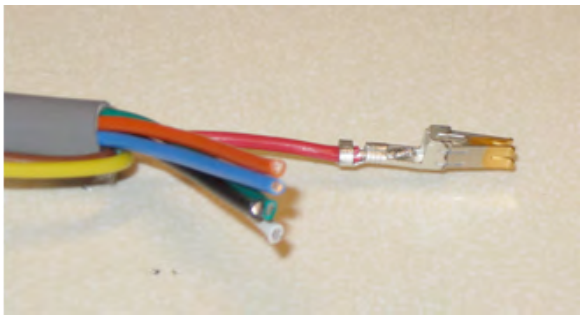


Figure 1. Female crimp terminal on wire of 8-conductor cable.

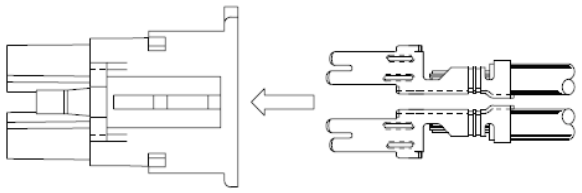
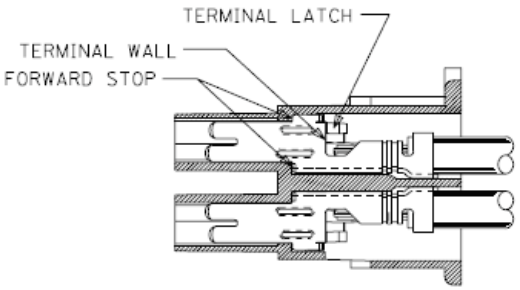
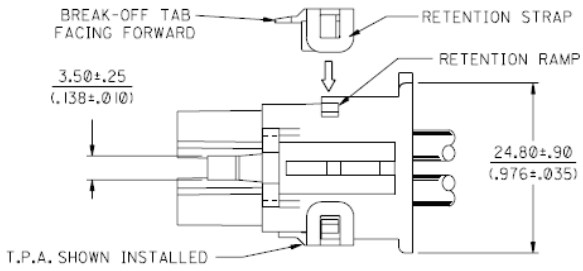
F. Insert the six female crimp terminals into the 2x3 Molex female power connector according to Table 1.

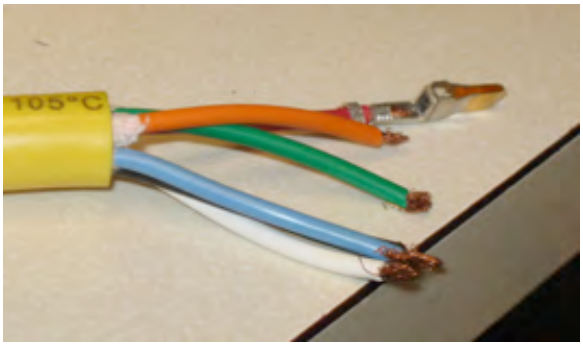
Table 1. Color / Voltage / Pin # Mapping of Two Cables and Connectors

Cable	Voltage	Wire Color	Connector Pin #
1	12v-right	Red	1
	12v-right-gnd	White	4
	12v-left	Green	2
	12v-left-gnd	Blue	5
	24v	Orange	3
	24v-gnd	Black	6
2	34v	Red	1
	34v-gnd	White	4
	5v	Green	2
	5v-gnd	Blue	5
	12v	Orange	3
	12v-gnd	Black	6

Note: For Cable 2, pins 7-12 correspond with pins 1-6 of the Molex connector, but are labeled 7-12 to differentiate from the wires in Cable 1.

Use a label maker to print labels on both sides of the connectors.

G. Terminals are to be orientated and loaded into the connector housing as shown.	 Figure 2. Orientation of crimp terminals when inserting into Molex connectors.
H. Terminals are loaded when seated against forward stop and terminal latches are snapped behind terminal walls (retention force at this stage = 0.5 kg).	 Figure 3. Completely inserted crimp terminals.
I. After terminals are loaded into housing, the T.P.A. (BOM part 4 and/or 5) is to be “broken or cut” in half, oriented, and installed in the direction shown until the retention straps snap over the retention ramps.	 Figure 4. Inserting the T.P.A.
Note: This connector must never be used without the installation of the T.P.A.	

Step 2. Power Supply Connection	
There are two terminal screws for each power module. Connect the cables to the power supply according to Table 1. Using a Phillips head screwdriver, unscrew the terminal screws. Place the ring terminal into the screw and screw the terminal screw back.	
Step 3. Arm Connection Assembly	
A. The power is connected to the head through the two yellow 20-foot Woodhead cables. Crimp the male crimp terminals on the ends of the exposed wires of the two Woodhead cables.	 Figure 5. Male crimp terminal on one wire of 6-conductor Woodhead cable.
B. Insert the wires into the male connector; the pin numbers are the same as in Table 1.	
C. Make sure to label which voltages go where. Insert the T.P.A. after all the cables have been properly inserted into the connectors.	
Note: The pin numbers start from the opposite direction than the female Molex connector; be sure to locate the ridge that represents pin 1.	

Step 4. Passive Board Connection

A. Make a 1.5 ft cable out of the 8-conductor 16 AWG cable. Crimp male crimp terminals on all eight wires. They should be inserted into the male Molex connector and labeled as described in Table 2.

Table 2: Color / Voltage/ Pin# mapping of cable that connects power to passive board

Wire Color	Label	Molex Connector pin #
Green	12V-R	1
Orange	5V	2
Red	24V	3
Brown	12V-L	4
Blue	GND 12V-R	5
Black	GND 5V	6
White	GND 24V	7
Yellow	GND 12V-L	8

B. On the other end of the 1.5 ft. cable, strip the grey casing by 2 inches. Strip one half inch off each of the eight wires. These eight wires will be inserted into the screw terminal on the passive board. Label this end as well; no further assembly is required.

Step 5. Head Plate Connection

Once the head connector panel has been assembled, a connector must be assembled from the two cable assemblies that the 20-ft yellow cables plug into.

First, crimp female terminals onto the following wires (Table 3, Cable 1 Receptacle is where Cable 1 is plugged into and Cable 2 Receptacle is where Cable 2 plugs into).

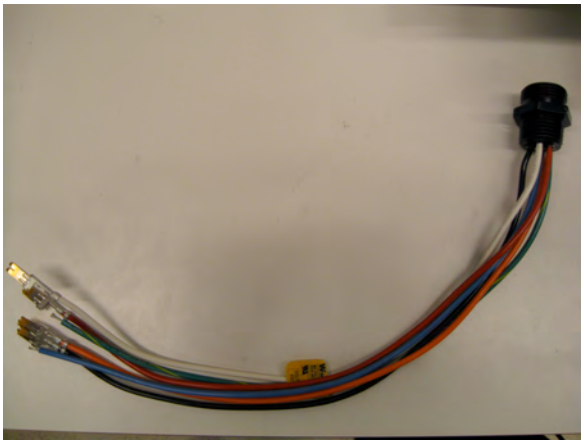


Figure 7: Cable assembly that is inserted into head plate, with female crimp terminals attached.

Note: The wires can be crimped before the cable assemblies are inserted into the head connector panel, but they MUST be fed through the head entry panel, and the connector nut that secures the connector to the panel before inserting the crimp terminals into the Molex connector. Otherwise, the cables will not feed properly through the head entry panel and the process will have to be restarted. Refer to SOP A8 Light Source Housing.

Table 3. Color / Voltage / Pin # Mapping of Two Cable Assemblies and Connectors

Receptacle	Voltage	Wire Color	Molex Connector	Molex Pin #
Cable 1	12v-left	Green	1	4
	12v-left-gnd	Blue	1	8
	24v	Orange	1	3
	24v-gnd	Black	1	7
	12v-right	Red	1	1
	12v-right-gnd	White	1	5
Cable 2	5v	Green	1	2
	5v-gnd	Blue	1	6
	34V	Red	2	1
	34V-gnd	White	2	4

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created new SOP for DC Power Delivery.	4/22/2009	Alan Stockdale Barbar Clough
V 1.0	Modified Record	Edited.	6/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A15
Grounding Cart

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough	06/12/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	A15 Appendix A

1. PURPOSE

The purpose of this document is to outline the procedures for grounding the cart used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel grounding the cart for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

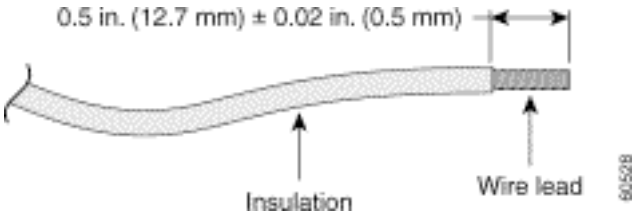
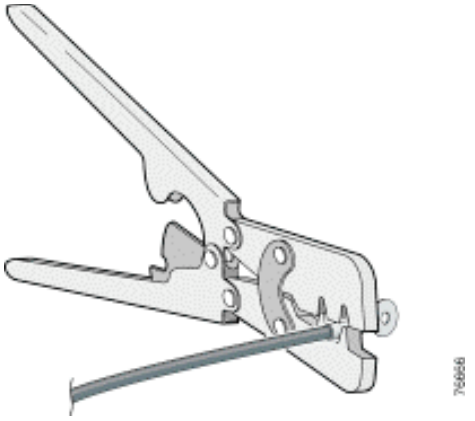
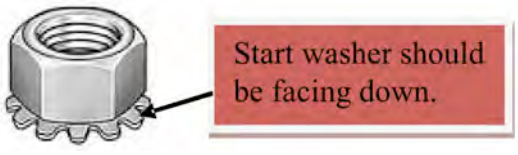
5. MATERIALS AND EQUIPMENT

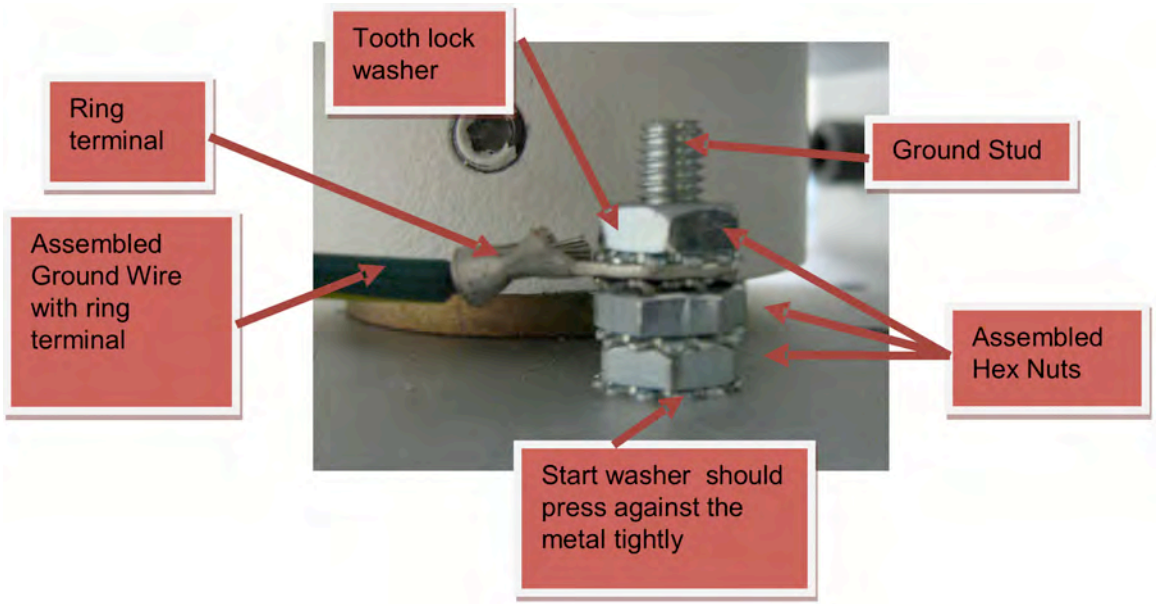
The following materials will be needed for completion of this SOP.

Part #	Manufacturer	Part #	Qty.	Picture
Stainless steel #10-32 Machine Screw Hex Nuts Assembled with Washers	McMaster Carr	96278A411	40	
Stainless Steel Tooth Lock Washers	McMaster Carr		12	
Hook-Up Wire 16AWG UL1015 GRN	Belden	8917 005100	10 ft	
Bare Ring Terminal #16 to #14, AWG, #10 Stud			18	

Craftsman Professional Crimper/Stripper/Cutter
A15 Appendix A Stud Locations in the Imaging System

6. PROCEDURES

Steps	
Note: For stud locations, refer to SOP A15 Appendix A Stud Locations in the Imaging System	
A. Use values given in A15 Appendix A for wire lengths and the 16 AWG hook-up wire and make 5 sets of wires.	
B. Use the stripper tool to strip 0.5 inches of the hookup wire (see Figure 1) on both ends.	 Figure 1. Stripping the Ground Wire
C. Slide the ground wire inside the ring terminal.	
D. Using the crimping tool, crimp the ring terminal to wire.	 Figure 2. Crimping the Ring Terminal
E. For each stud: Screw <u>two</u> assembled hex nuts with washers to the stud such that the star washer is facing down. The bottom washer should tightly grab the metal.	



F. Screw in a tooth lock washer.	
G. Place the assembled ring terminal (consult A15 Appendix A to place right size wires on correct studs).	
H. Screw in a third assembled hex nut.	
I. Tighten all screws.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A15 Grounding Cart	04/22/2009	Barbara L. Clough
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A15 Appendix A
Stud Locations in the Imaging System

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/19/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A15 Grounding Cart	None	None

For safety, and in accordance with UL60601 standards, all accessible noncurrent carrying conductive parts of the imaging system should be **protectively earthed** (grounded). This means that all metal parts of the imaging system, starting from the light source (aluminum housing), and going all the way to the cart, need to be wired in such a way that a continuous ground path is provided between these points. Grounding points are provided in the form of ground studs on multiple locations in the imaging system (shown in the picture). 16 AWG ground wire and closed ring crimp connectors are used in this assembly to bridge different parts of the system (e.g., arm articulation joints) with stud-to-stud connection.

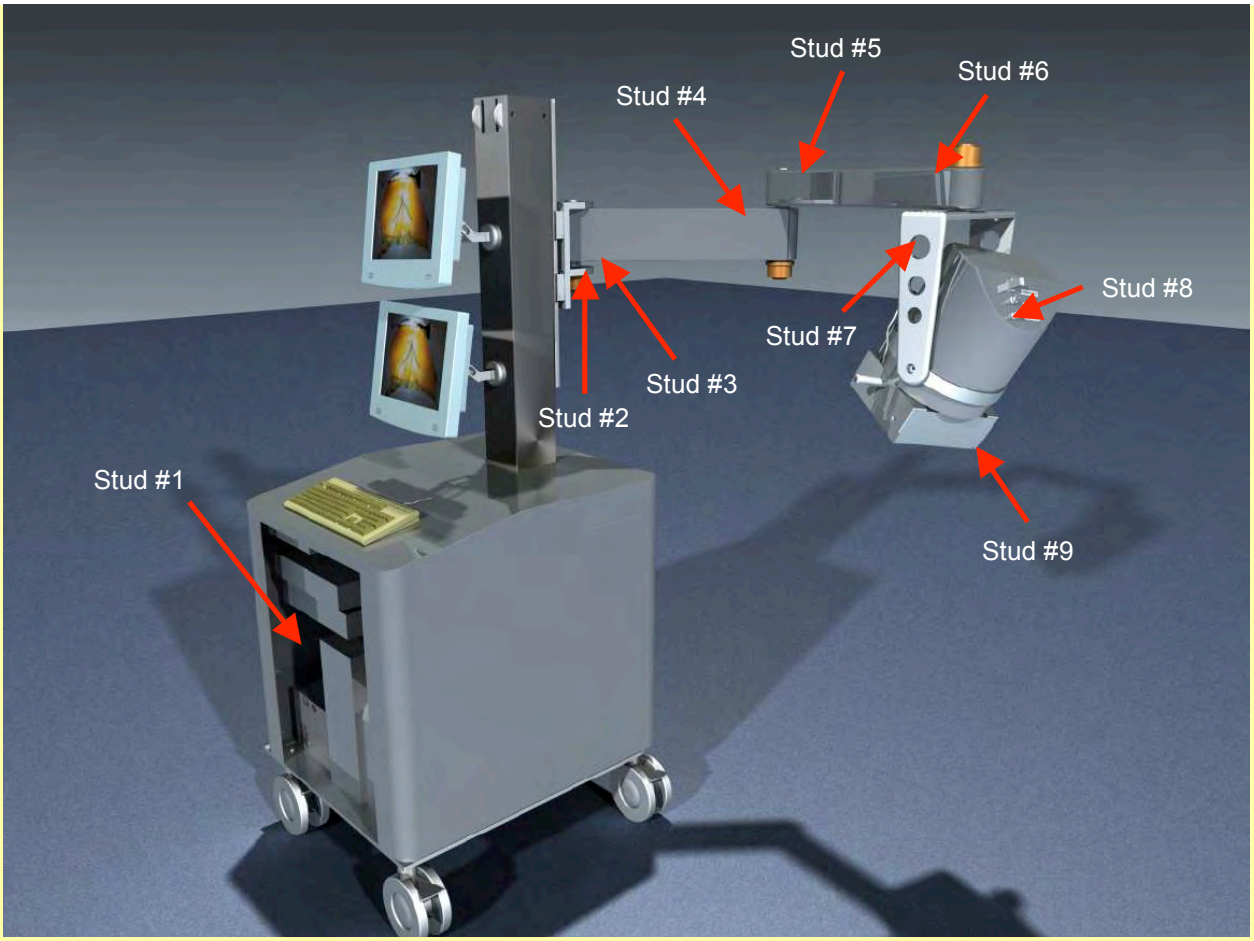
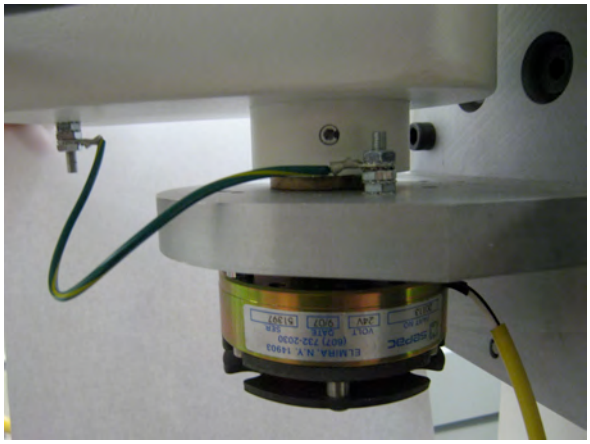
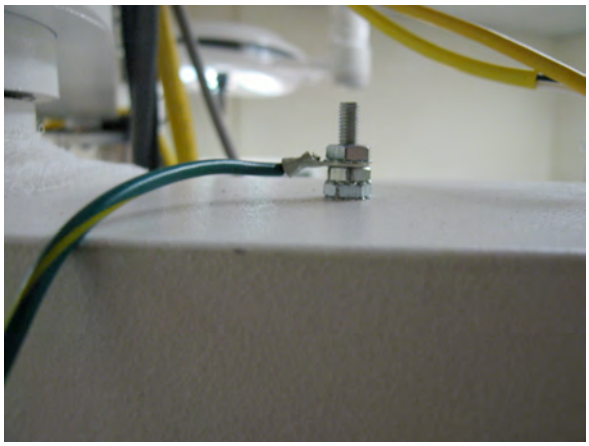
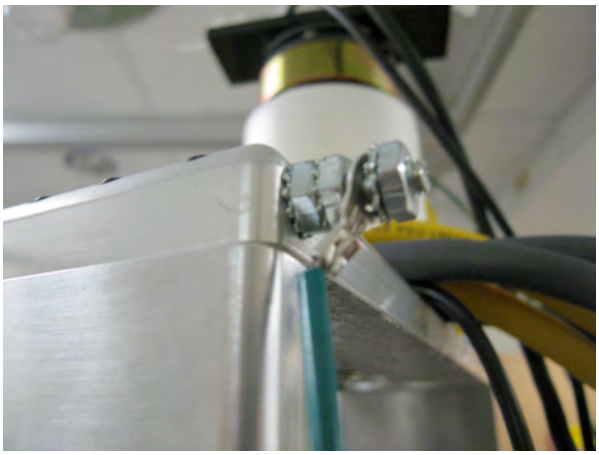
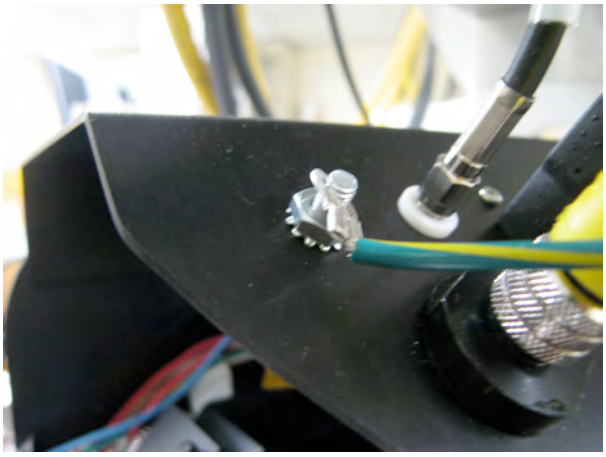
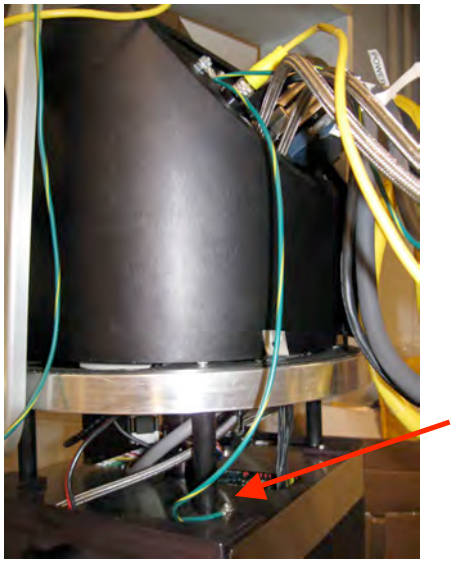


Figure 1. Stud locations in the imaging system

Table 1.

Studs	Location	Note	Picture
Stud #1	Left side/wall of the cart	This is the **MAIN** stud where the cart is connected to the earth ground. The (ground) green wire of the power entry module and also green wire (ground) of the isolation transformer should be connected to this stud.	
Stud #2 Stud #3		Stud #2 and Stud #3 should be connected with an 8-inch wire.	
Stud #4 Stud #5		Stud #4 and Stud #5 should be connected with a 20-inch wire.	

Stud #6 Stud #7		Stud #6 and Stud #7 should be connected with a 50-inch wire.	
Stud #8	Imager breakout panel	Stud #6 and Stud #8 should be connected with a 50-inch wire.	
Stud #9	Aluminum housing	20-inch wire from breakout panel to RF shield / housing.	

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A15 Appendix A Stud Locations in the Imaging System for SOP A15 Grounding Cart	04/19/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A16
Full Cart Assembly

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Alan Stockdale	08/26/2010		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-1 Active Board	None	None
A1-2 Passive Board		
A3 Jumper, LED, Filter assembly		
A4 Active-passive Board		
A5 LED Module Assembly		
A6 LED Ribbon Cable		

1. PURPOSE

The purpose of this document is to outline the procedures for assembling the interior of the FLARE cart used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

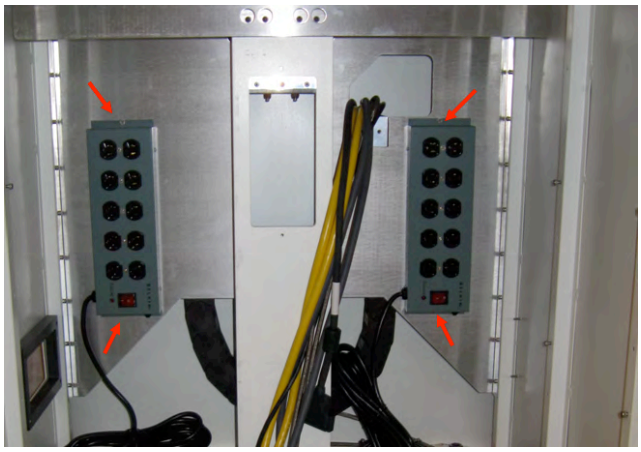
5. MATERIALS AND EQUIPMENT

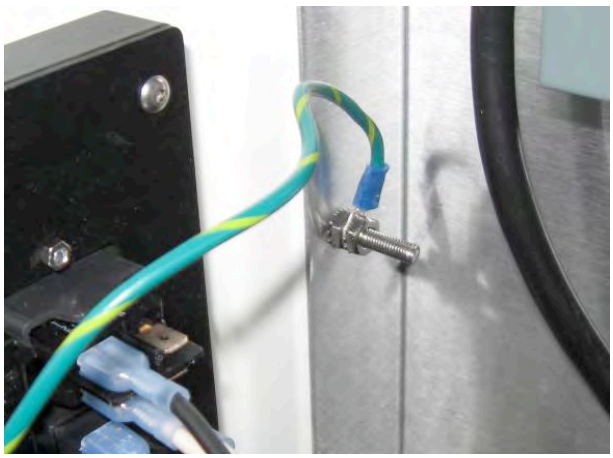
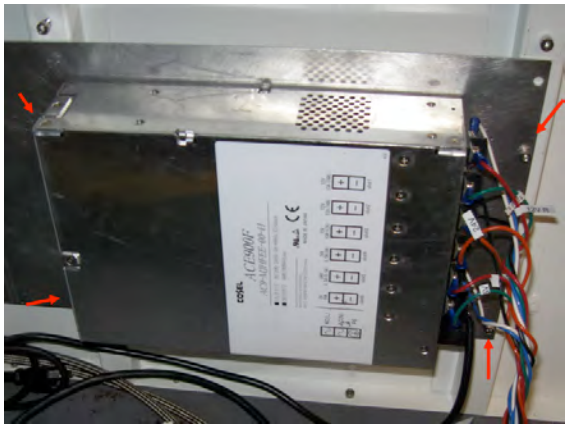
The following materials will be needed for completion of this SOP.

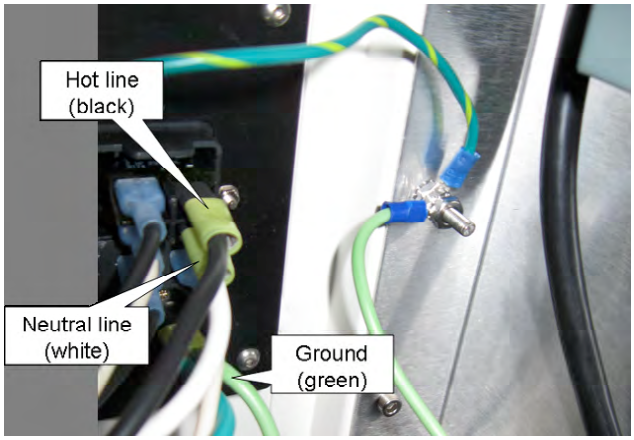
A12 Isolation Transformer
A13 Cart Entry Panel
A14 DC Power Delivery
A17 Cable Trough Assembly
A18 DVI Splitter
A19 CA-1000
A21 Thermocube Preinstallation

Name	Manufacturer	Part #	Qty.	Picture
Power strip	Belkin	F9D1000-15	2	
Socket head cap screw (SHCS), stainless steel, 10-32 x 1/2 inch	McMaster	92196A269	8	
Stud, SS, 10-32 x 11/4 inch	McMaster	95412A471	1	
KEP nut, 10-32	McMaster	96278A411	3	
Button head cap screw, 8-32x1/4 inch	McMaster	92949A190	4	
DVI dual video splitter	ATEN	VS162	1	
Computer	Dell	T5300	1	
Dell Ultrasharp 20-inch monitors 1600x1200 res.	Dell	2007FP	2	
Monitor arm	Ergotron	28-096-180	1	
Monitor adapter plate	Ergotron	Comes with arm	2	
Also: all power and/or video cables that come with associated assemblies or equipment.				

6. PROCEDURES

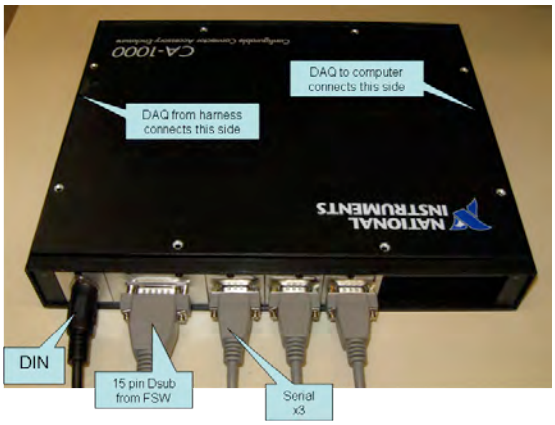
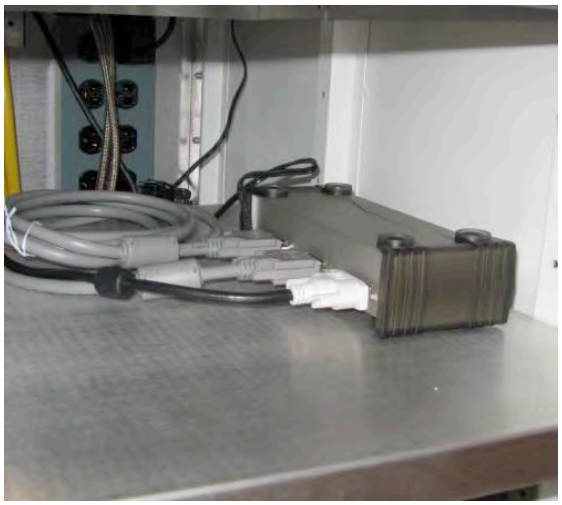
Step 1. Cart Assembly - Interior	
A. If not complete, finish the installation of the Cable Trough (SOP A17) into the cart. Ensure the cables from the trough extend into the cart interior.	
B. Attach the power strips to the back interior panel as shown. As indicated by the arrows, use the 10-32x 1/2 inch SHCS to secure the strips.	

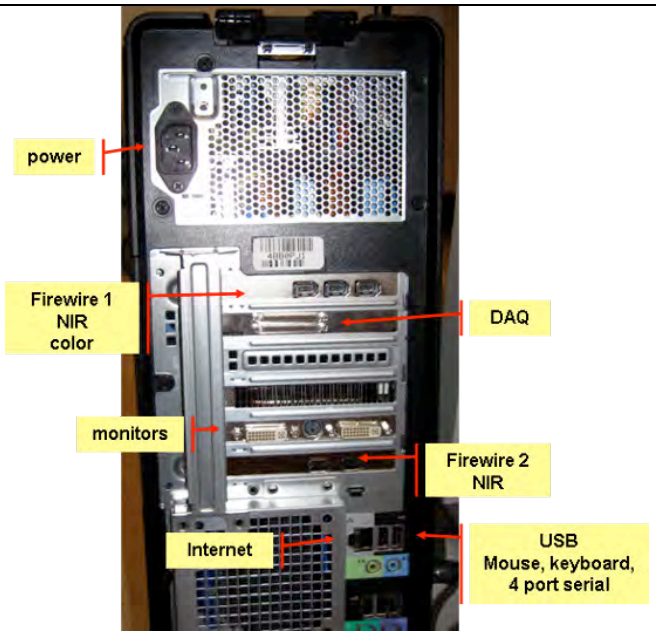
C. Secure the Cart Entry Panel (CEP) (SOP A13) with four 8-32x 1/4 inch BHCS.	
D. Insert the ground stud into the cart near the CEP as shown, using a 10-32 KEP nut to help secure the stud. Attach the flying lead from the CEP ground (green/yellow wire) to the ground stud using a second KEP nut as shown.	
E. Secure the DC power supply assembly to the interior right side of the cart using four (4) 10-32 x 1/2 inch SHCS.	

F. Connect the two cart fan power cords to each fan, and connect each to the closest power strip.	
G. Place the ISO transformer (SOP A12) in the cart and attach the power cord from the ISO to the power input module on the CEP. Connect the flying lead from the ISO ground wire to the cart ground stud using a third KEP nut When the power cable is connected, slide the ISO towards the right rear as shown, and plug in power strips, the DC supply, and the computer power cable.	

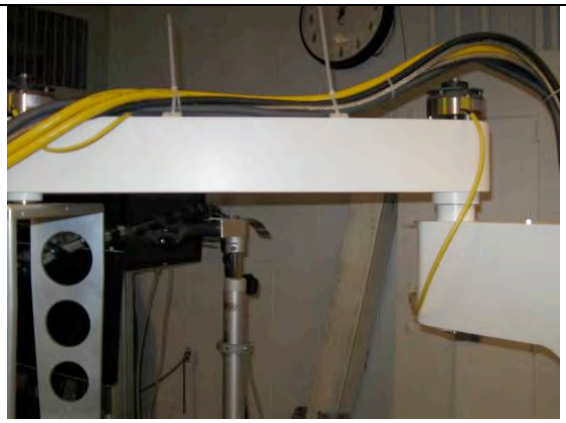
H. Install the sold state chiller. Connect the cooling lines from the harness to the ports on the chiller, and fully tighten with a crescent wrench. (Cooling fluid will be added later during the final system checkout).	

I. Install the internal shelving. Use the 10-32x1/2 inch SCHS. First place the top shelf in at the second set of holes from the top of the cart. The lower shelf is attached to the right side of the cart interior, and to the bottom of the top shelf.	
J. Install the ORCA camera drivers. Place the drivers on the right side of the top shelf. Complete the connections: 1 DB connector from the harness, and 1 firewire connector to the computer for each driver.	

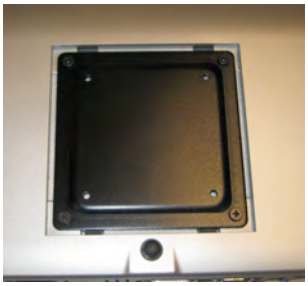
K. Install the CA-1000 assembly (SOP A19). Place in the middle of the top shelf. Complete the connections to the assembly – DIN 5-power connector to AC converter, DB15 from CEP, 3 x. DB9 serial connectors to 4-port serial to USB interface, DAQ cables – one from harness, two to computer.	
L. Install the DVI port. Place on right side of middle shelf. Connect bottom (control) monitor and external monitor to the output ports – the input port comes from the computer monitor card. Connect the power supply to power strip.	
M. Complete connections to the 4-port serial to USB interface. Serial connectors – three (3) from CA-1000 and one from chiller. USB connects to available computer port. Connect power supply to power strip.	
N. Install computer.. Complete connections to computer, keyboard, mouse, monitor DVI connections (2), network connection (to CEP), USB	

connection from 4-port serial to USB interface, DAQ connections, camera connections – two firewire from ORCA drivers and single firewire from color camera – these plug into two separate firewire controllers (ensure that the ORCA cameras are not connected to the same card).	

Step 2. Cart Assembly – Exterior	
A. Install the monitor supports into the positions located on the central post.	
B. Secure the cable harness to the top of the arm. Use cable ties to first bundle the harness together. Then using cable tie anchors, secure the bundled harness with cable ties to the anchors. Use cable ties to secure the harness to the fixtures mounted to the top of the brakes. Note the spacing of the cable ties on the harness, and the spacing of the cable tie anchors. Make sure slack is left at each arm joint. This will allow complete range of motion of the arm without pulling or damaging the cables.	

<table>
<tr><td></td><td>  </td></tr>
<tr><td rowspan="2">C. Attach the monitors to the monitor mounts.

1) Prepare the monitors. Install the monitor mount adapter on the back of each monitor. First, remove the screws from the mounting holes on the rear of the monitor (i). Second, attach the adapter plate to the rear of the monitor and make sure the plate is flush with the rear of the monitor (ii).

2) Mount the monitor. Hold the monitor and use the M4 x 8 mm screws to secure the monitor.</td><td>i) ii)  </td></tr>
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7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A16 Full Cart	08/26/2010	Alan Stockdale
V 1.0	Modified Record	Edited	04/27/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A17
Cable Trough

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough	05/15/2008		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	None

1. PURPOSE

The purpose of this document is to outline the procedures for assembling the Cable Trough used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the Cable Trough for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

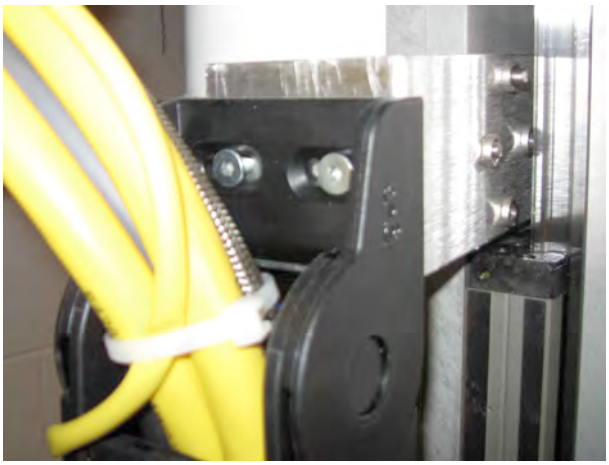
Item	Manufacturer	Part #	Qty.
DB68 female to DB68 female shielded cable, 5 m (CA-1000 to imaging head)	National Instruments	183432-05	1
Firewire Cable for color Camera, 20 ft	Monster Cable	125003	1
Thermocube PTFE Carbon-coated 22 ft hose	Cambridge Valve	SS-TC4-TA4-TA4-264	2
Power cables, 6 conducor, 20 ft	Woodhead	106000A01F200	2
Orca cables, 20 ft	Hamamatsu		2

Tools needed
Flathead Screwdriver
Small hammer

6. PROCEDURES

Step 1. Manufacturing Procedures	
A. Remove the cable trough from the cart by unscrewing the cable trough from the back plate in the interior rear of the cart. Unhook the trough from the exterior mast and let it drop down. Once down, remove the L-shaped bracket. At this point, it is possible to pull out the cable trough from outside the cart.	
B. Lay the cable trough on the ground, with the side with the hinge snap connectors facing up. Using a small screwdriver, open up all the hinges.	
C. Remove the bracket on the end of the cable trough using a flathead screwdriver.	
D. Lay the eight (8) cables (2 cooling, 2 power, 2 camera, 1 firewire, 1 DAQ) in the trough. 1) Place the cables so that 9 ft inches of each cable is above the cable trough. The cooling cables should be 1 foot longer than the other cables, as they need to travel a longer distance at the head. 2) Ensure that the cables are not twisted.	

E. Using a hammer carefully tap the hinge snap connectors closed – be careful, the hinges can break if hit too hard.	
F. Put the bottom section of the trough back on the trough.	

Step 2. Mounting the Cable Trough	
A. Lift the cable trough (with the cables) and place it over the opening – ensure that the cables do not slide, as the lengths should not change. The hinge snap openings of the trough should be facing to the left of the cart.	
B. Pass the ends of the cables into the cart, then slowly lower the trough into the opening. If the trough gets caught, unblock the trough from the inside as it can get caught on fans, etc.	
C. Continue lowering the trough into the opening until the opening for the screws is level with the bracket on the arm, and then insert the two (2) screws and tighten.	
D. Enter the inside of the cart, and attach the L-shaped bracket to the end of the cable trough. The shorter side of the bracket should be facing the outside of the cart.	
E. Pass the cables up behind the back plate and through the opening. Once all the cables are through, pass the trough up, hooking the bracket into the slit in the back plate. Insert two (2) screws to attach the trough to the back plate.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A17 Cable Trough Assembly	05/15/2008	Barbara L. Clough
V 1.0	Modified Record	Edited	04/26/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A18
DVI Splitter and Monitor Connections

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough	05/08/2008		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	A18 Appendix A

1. PURPOSE

The purpose of this document is to outline the procedures for connecting the DVI signal splitter to the computer and to each monitor used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

A18 Appendix A DVI Splitter Wiring Diagram

Item	Qty
DVI Splitter with power supply	2
6 ft monitor power cord (provided)	2
6 ft monitor DVI cable (provided)	2
18 ft satellite monitor power cord	2
15 ft DVI cable	2
3 ft DVI cable	2

6. PROCEDURES

Steps	
Connect the DVI splitters to the local monitors and the satellite monitors according to the diagram found in SOP A18 Appendix A.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A18 DVI Splitter and Monitor Connections	05/08/2008	Barbara L. Clough
V 1.0	Modified Record	Edited	04/26/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A18 Appendix A
DVI Splitter Wiring Diagram

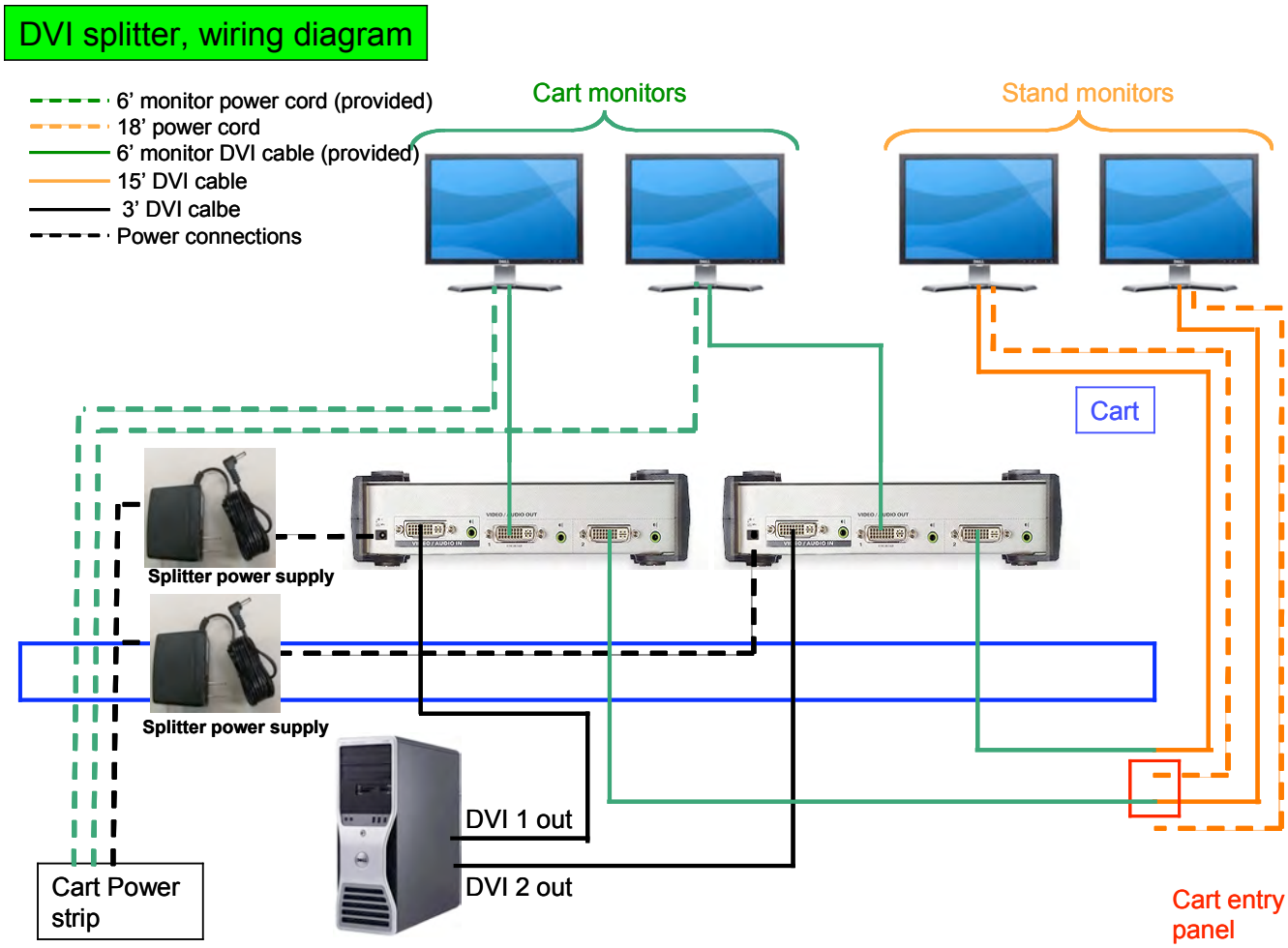
Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/20/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A18 DVI Splitter and Monitor Connections	None	None

Figure 1. DVI Splitter Wiring



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A18 Appendix A DVI Splitter Wiring Diagram for SOP A18 DVI Splitter and Monitor Connections	04/20/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A19
CA-1000

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough Alan Stockdale	04/23/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A1-6 Footswitch Board	None	A19 Appendix A
		A19 Appendix B
		A19 Appendix C

1. PURPOSE

The purpose of this document is to outline the procedures for assembling and wiring of the CA-1000 used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the FLARE™ imaging system.

3. RESPONSIBILITIES

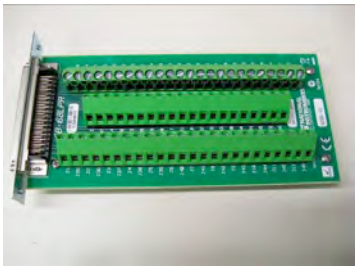
The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

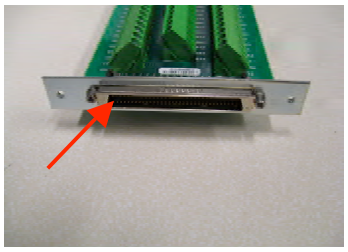
4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

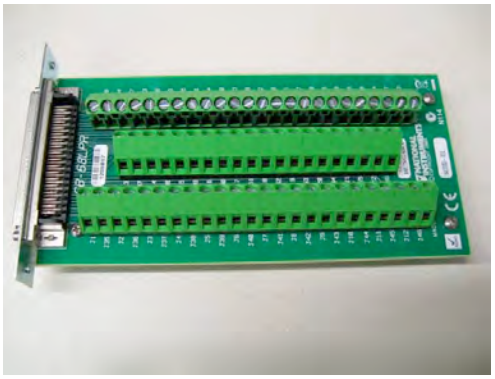
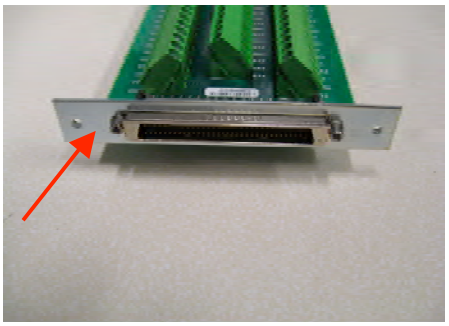
The following materials will be needed for completion of this SOP.

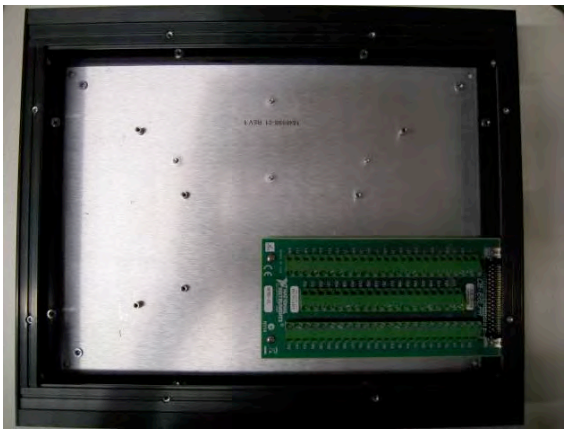
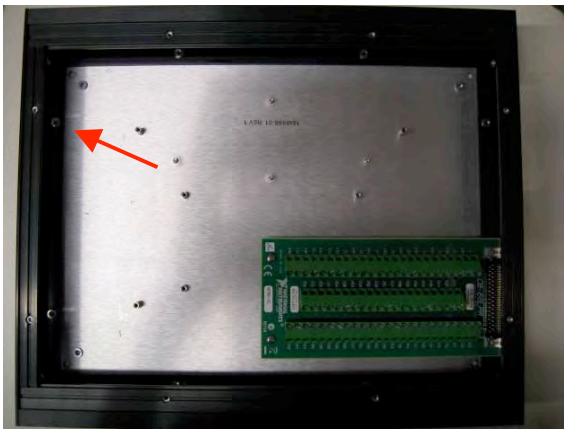
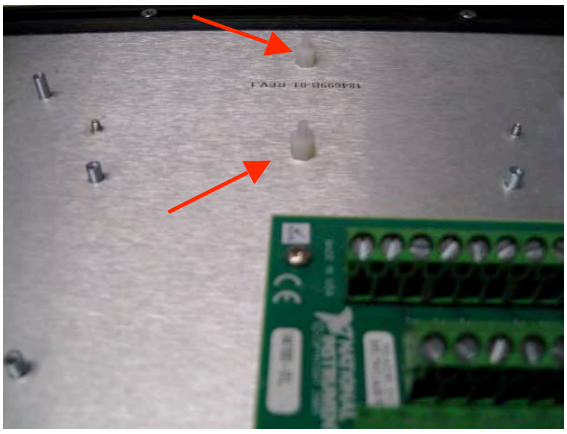
A1-6 Footswitch Board				
Name	**Manufacturer**	**Part #**	**Qty.**	**Picture**
CA-1000	National Instruments		1	
DAQ I/O Connector Block	National Instruments	CB-68LPR	3	

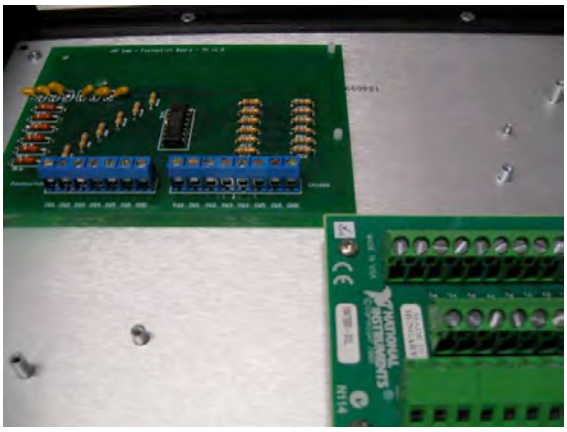
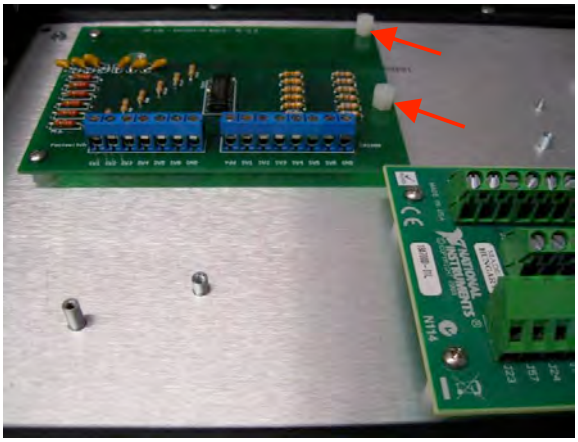
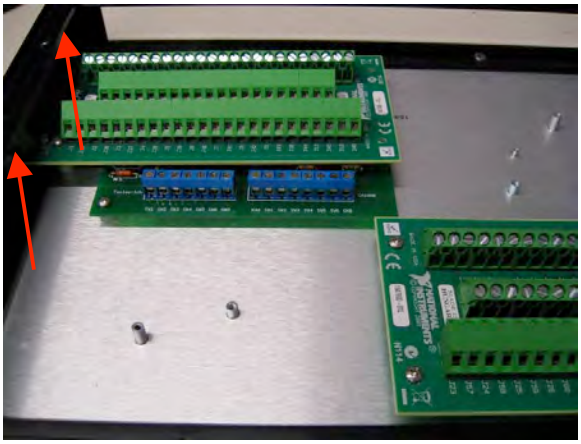
1/4 inch Nylon-Hex spacers 4-40, with threaded stud	Mouser	534-4800	4	
1/4 inch spacers Nylon-Hex spacers 4-40, without threaded stud	Mouser	534-1902A	2	
Breakout panel panellete			3	

Required Tools
Wire stripper/cutter
Screwdriver
Hexdriver

6. PROCEDURES

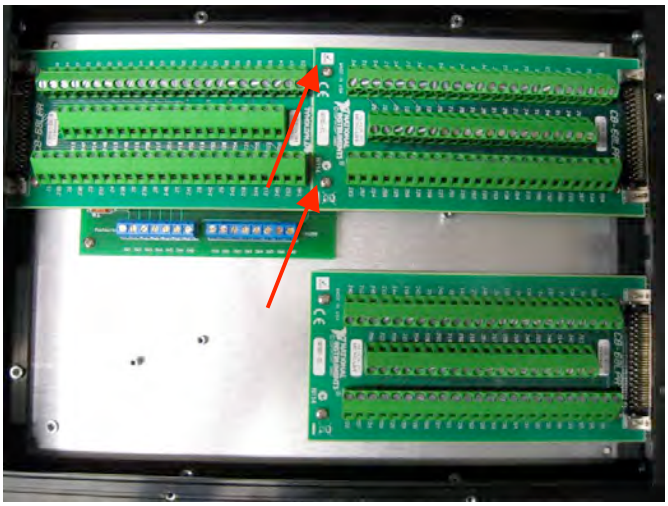
Steps	
A. Solder the Footswitch as per diagram. This must be completed before the CA-1000 is assembled (SOP A1-6).	
B. Take a breakout panel and attach the panellete. The bottom picture shows the breakout panel with the attached panellete. Attach the panellete by removing the screws on either side of the breakout panel. Place the metal panellete as shown and reinsert the screws.	 

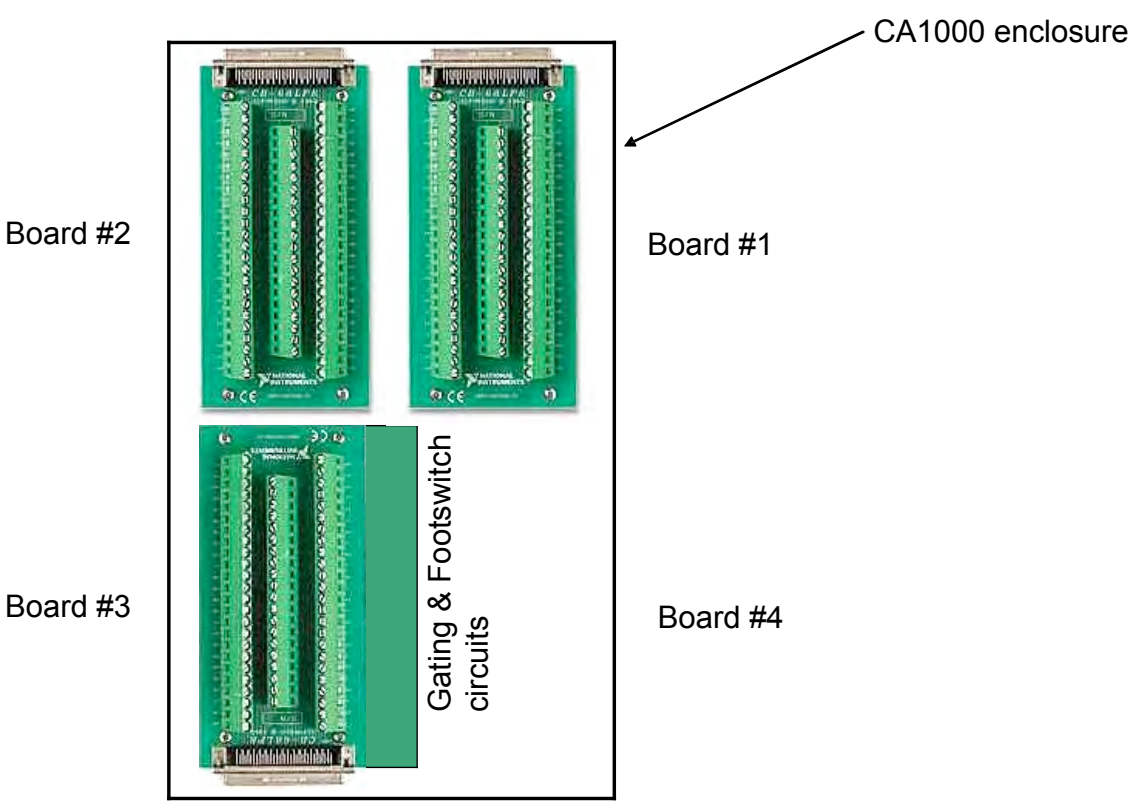
C. Remove one of the boards from the CA-1000; the box should look as pictured.	
D. Remove the panel on the inside of the side of the CA-1000 box by removing the screws from the outside of the box (the arrow shows the location). This is where the panelette of the breakout panel will be screwed in later. Keep the screws for Step H.	
E. Screw the 2 1/4 inch nylon spacers with threaded studs on top of the protruding metal studs, as shown in the picture.	

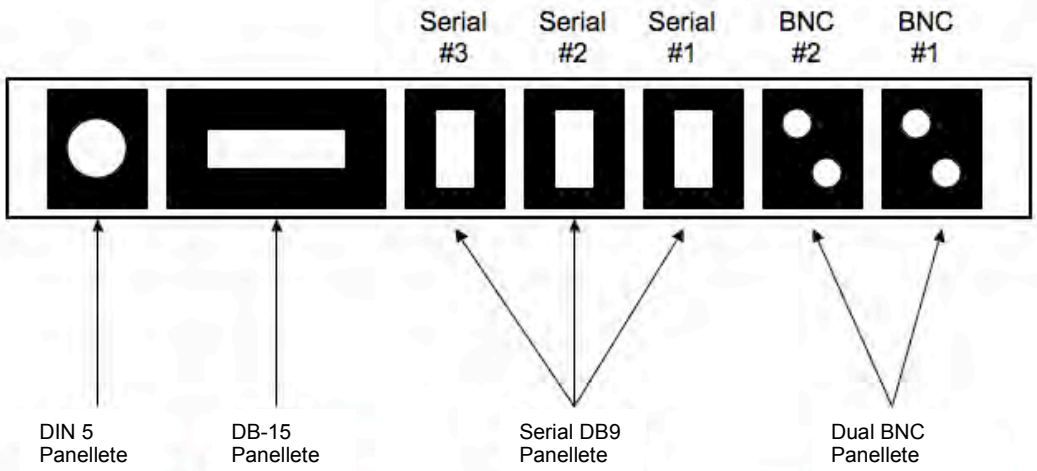
F. Place the Footswitch board over the two nylon spacer studs, in the CA-1000 box, as shown in the picture.	
G. Screw two (2) 1/4 inch spacers (without threaded studs) onto those protruding from the Footswitch board, as shown in the picture.	
H. Place a breakout panel (there are two, both the same) over the Footswitch board and screw it into the openings in the CA-1000 box created by removing the metal panel in Step D. Use the screws from Step D; hole locations are indicated by arrows.	

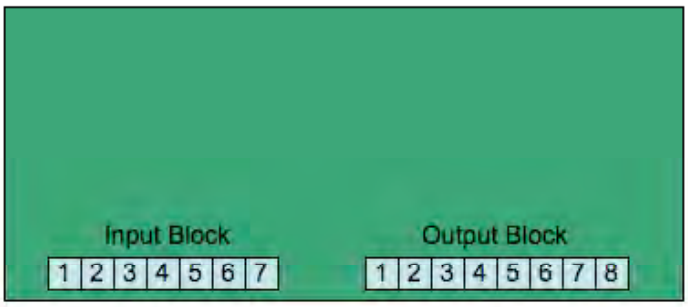
I. Place the third board in the box; the back two holes should line up with the holes of the second board. Use small 4-40 screws to attach them together.

The complete CA-1000 box with breakout panels is pictured below.





J. Insert the following panelletes on the Board #1 and #4 side of the CA-1000 (see diagram on previous page).	
	
K. Insert the wires according to the wiring tables found in SOPs A19 Appendix A, A19 Appendix B, and A19 Appendix C for Board Connections 1-3.	
L. Footswitch board pinout: The connections to the 7-pin block terminal (left side in diagram) come from the DB-15 panellete, while the connections to the 8-pin block terminal (right side in the diagram) come from Board 1.	

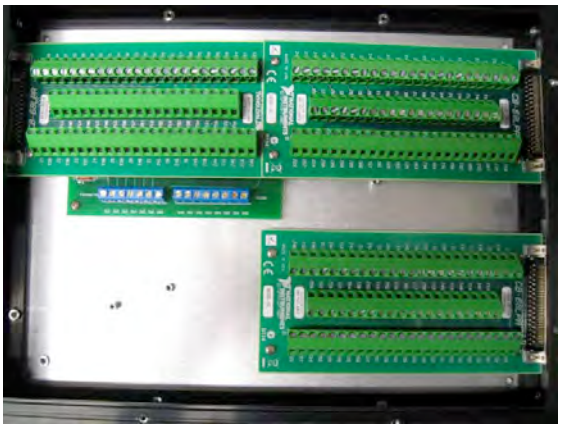


Input pin#	DB15 pin#, color
1	1, red
2	2, blue
3	3, orange
4	4, green
5	5, light maroon
6	6, pink
7	7, grey

Output Pin #	Description
1	Footswitch_5V
2	Footswitch_Sense1
3	Footswitch_Sense2
4	Footswitch_Sense3
5	Footswitch_Sense4
6	Footswitch_Sense5
7	Footswitch_Sense6
8	Footswitch_DGND

DB15 Connector

Board #1 and #2



7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A19 CA-1000	04/23/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/26/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A19 Appendix A
Board #1 Connections

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/20/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A19 CA-1000 – v 2.0	None	None

Table 1. Board #1 Connections

Board pin#	DAQ Destination	Connects to	General description	Group
B1_1				
B1_2	DAQ DGND	B3_40	C5_DGND	Passive Board
B1_3	DAQ DGND	B3_34	C2_DGND	Passive Board
B1_4	DAQ DGND	B3_46	Passive Board Gnd	Passive Board
B1_5	DAQ P1.6	B3_48	Program	Passive Board
B1_6	DAQ P1.5	B3_47	Reset	Passive Board
B1_7				
B1_8	DAQ +5V	B3_19, Footswitch_5V	PressureSensor_5V, Footswitch_5V	Pressure sensor, footswitch
B1_9				
B1_10	DAQ P1.1	B3_33	C2_ON/OFF	Passive Board
B1_11	DAQ P1.0	B3_31	C1_ON/OFF	Passive Board
B1_12				
B1_13				
B1_14	DAQ +5V	B3_13	TempSensor1_5V, TempSensor2_5V, TempSensor3_5V, TempSensor4_5V	Temp sensor
B1_15				
B1_16				
B1_17	DAQ P0.1	Footswitch_Sense2		Footswitch
B1_18				
B1_19	DAQ P0.4	Footswtich_Sense5		Footswitch
B1_20				
B1_21				
B1_22				
B1_23				
B1_24				
B1_25	DAQ AI 6	B3_27	HumiditySensor1_Sense	Humidity sensor
B1_26				
B1_27				
B1_28	DAQ AI 4	B3_21	PressureSensor_Sense	Pressure sensor
B1_29	DAQ AGND	B3_23	Photodiode_Gnd	Photodiode
B1_30	DAQ AI 3	B3_18	TempSensor4_Sense	Temp sensor
B1_31	DAQ AI 10	B3_49	Temperature out	Passive Board
B1_32	DAQ AGND	B3_20	PressureSensor_Gnd	Pressure sensor
B1_33	DAQ AI 1	B3_16	TempSensor2_Sense	Temp sensor

B1_34	DAQ AI 8	B3_29	HumiditySensor3_Sense	Humidity sensor
B1_35				
B1_36				
B1_37	DAQ DGND	B3_32	C1_DGND	Passive Board
B1_38				
B1_39				
B1_40				
B1_41	DAQ P1.4	B3_39	C5_ON/OFF	Passive Board
B1_42	DAQ P1.3	B3_37	C4_ON/OFF	Passive Board
B1_43	DAQ P1.2	B3_35	C3_ON/OFF	Passive Board
B1_44				
B1_45	DAQ DGND	B3_36	C3_DGND	Passive Board
B1_46	DAQ DGND	B3_38	C4_DGND	Passive Board
B1_47	DAQ P0.3	Footswitch_Sense4		Footswitch
B1_48				
B1_49	DAQ P0.2	Footswitch_Sense3		Footswitch
B1_50	DAQ DGND	Footswitch_DGND		Footswitch
B1_51	DAQ P0.5	Footswitch_Sense6		Footswitch
B1_52	DAQ P0.0	Footswitch_Sense1		Footswitch
B1_53				
B1_54				
B1_55				
B1_56				
B1_57	DAQ AI 7	B3_28	HumiditySensor2_Sense	Humidity sensor
B1_58				
B1_59				
B1_60	DAQ AI 5	B3_24	Photodiode_Sense	Photodiode
B1_61				
B1_62				
B1_63				
B1_64	DAQ AGND	B3_26	HumiditySensor1_Gnd, HumiditySensor2_Gnd, HumiditySensor3_Gnd, HumiditySensor4_Gnd	Humidity sensor
B1_65	DAQ AI 2	B3_17	TempSensor3_Sense	Temp sensor
B1_66	DAQ AI 9	B3_30	HumiditySensor4_Sense	Humidity sensor
B1_67	DAQ AGND	B3_14	TempSensor1_Gnd, TempSensor2_Gnd, TempSensor3_Gnd, TempSensor4_Gnd	Temp sensor
B1_68	DAQ AI 0	B3_15	TempSensor1_Sense	Temp sensor

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A19 Appendix A Board #1 Connections SOP A19 CA-1000 – v 2.0	04/20/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A19 Appendix B
Board #2 Connections

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/20/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A19 CA-1000 – v 2.0	None	None

Board #2 Connections

Board pin#	Destination	Connects to	General description	Group
B2_1				
B2_2				
B2_3				
B2_4				
B2_5				
B2_6				
B2_7				
B2_8	DAQ +5V	B3_25	HumiditySensor1_5V, HumiditySensor2_5V, HumiditySensor3_5V, HumiditySensor4_5V	Humidity sensor
B2_9				
B2_10				
B2_11				
B2_12				
B2_13				
B2_14	DAQ +5V	B3_22	Photodiode_5V	Photodiode
B2_15				
B2_16				
B2_17				
B2_18				
B2_19				
B2_20				
B2_21				
B2_22				
B2_23				
B2_24				
B2_25				
B2_26				
B2_27				
B2_28				
B2_29				
B2_30				
B2_31				
B2_32				
B2_33				
B2_34				
B2_35				
B2_36				
B2_37				

Board pin#	Destination	Connects to	General description	Group
B2_38				
B2_39				
B2_40				
B2_41				
B2_42				
B2_43				
B2_44				
B2_45				
B2_46				
B2_47				
B2_48				
B2_49				
B2_50				
B2_51				
B2_52				
B2_53				
B2_54				
B2_55				
B2_56				
B2_57				
B2_58				
B2_59				
B2_60				
B2_61				
B2_62				
B2_63				
B2_64				
B2_65				
B2_66				
B2_67				
B2_68				

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A19 Appendix B Board #1 Connections SOP A19 CA-1000 – v 2.0	04/20/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A19 Appendix C
Board #3 Connections

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/20/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A19 CA-1000 – v 2.0	None	None

Board #3 Connections

Head DAQ I/O Board_pin#	Destination	Connects to	General description	Group
B3_1	DB9 #1	M1_DB9_5	Serial1_1	Motor1
B3_2	DB9 #1	M1_DB9_2	Serial1_2	Motor1
B3_3	DB9 #1	M1_DB9_3	Serial1_3	Motor1
B3_4	DB9 #1		Serial1_4	Motor1
B3_5	DB9 #2	M2_DB9_5	Serial2_1	Motor2
B3_6	DB9 #2	M2_DB9_2	Serial2_2	Motor2
B3_7	DB9 #2	M2_DB9_3	Serial2_3	Motor2
B3_8	DB9 #2		Serial2_4	Motor2
B3_9				
B3_10				
B3_11				
B3_12				
B3_13	DAQ +5V	B1_14	TempSensor1_5V, TempSensor2_5V, TempSensor3_5V, TempSensor4_5V	Temp sensor
B3_14	DAQ AGND	B1_67	TempSensor1_Gnd, TempSensor2_Gnd, TempSensor3_Gnd, TempSensor4_Gnd	Temp sensor
B3_15	DAQ AI 0	B1_68	TempSensor1_Sense	Temp sensor
B3_16	DAQ AI 1	B1_33	TempSensor2_Sense	Temp sensor
B3_17	DAQ AI 2	B1_65	TempSensor3_Sense	Temp sensor
B3_18	DAQ AI 3	B1_30	TempSensor4_Sense	Temp sensor
B3_19	DAQ +5V	B1_8	PressureSensor_5V	Pressure sensor
B3_20	DAQ AGND	B1_32	PressureSensor_Gnd	Pressure sensor
B3_21	DAQ AI 4	B1_28	PressureSensor_Sense	Pressure sensor
B3_22	DAQ +5V	B2_14	Photodiode_5V	Photodiode
B3_23	DAQ AGND	B1_29	Photodiode_Gnd	Photodiode
B3_24	DAQ AI 5	B1_60	Photodiode_Sense	Photodiode

B3_25	DAQ +5V	B2_8	HumiditySensor1_5V, HumiditySensor2_5V, HumiditySensor3_5V, HumiditySensor4_5V	Humidity sensor
B3_26	DAQ AGND	B1_64	HumiditySensor1_Gnd, HumiditySensor2_Gnd, HumiditySensor3_Gnd, HumiditySensor4_Gnd	Humidity sensor
B3_27	DAQ AI 6	B1_25	HumiditySensor1_Sense	Humidity sensor
B3_28	DAQ AI 7	B1_57	HumiditySensor2_Sense	Humidity sensor
B3_29	DAQ AI 8	B1_34	HumiditySensor3_Sense	Humidity sensor
B3_30	DAQ AI 9	B1_66	HumiditySensor4_Sense	Humidity sensor
B3_31	DAQ P1.0	B1_11	C1_ON/OFF – C1-A1	Passive Board
B3_32	DAQ DGND	B1_37	C1_DGND– C1-A0	Passive Board
B3_33	DAQ P1.1	B1_10	C2_ON/OFF– C2-A1	Passive Board
B3_34	DAQ DGND	B1_3	C2_DGND– C2-A0	Passive Board
B3_35	DAQ P1.2	B1_43	C3_ON/OFF– C3-A1	Passive Board
B3_36	DAQ DGND	B1_45	C3_DGND– C3-A0	Passive Board
B3_37	DAQ P1.3	B1_42	C4_ON/OFF– C4-A1	Passive Board
B3_38	DAQ DGND	B1_46	C4_DGND– C4-A0	Passive Board
B3_39	DAQ P1.4	B1_41	C5_ON/OFF– C5-A1	Passive Board
B3_40	DAQ DGND	B1_2	C5_DGND– C5-A0	Passive Board
B3_41	DB #3	ACT_DB9_3	Serial3_1 – RX0	Passive Board
B3_42	DB #3	ACT_DB9_7	Serial3_2 – RTS	Passive Board
B3_43				
B3_44	DB #3	ACT_DB9_5	Serial3_4 – DB9-	Passive Board
B3_45	DB #3	ACT_DB9_2	Serial3_5 – TX0	Passive Board
B3_46	DAQ DGND	B1_4	Passive Board Gnd	Passive Board
B3_47	DAQ P1.5	B1_6	Reset	Passive Board
B3_48	DAQ P1.6	B1_5	Program	Passive Board
B3_49	DAQ AI 10	B1_31	Temperature out	Passive Board
B3_50	DB #3	ACT_DB9_4	Serial3_3 – DTR	Passive Board
B3_51				
B3_52				
B3_53				
B3_54				

B3_55				
B3_56				
B3_57				
B3_58				
B3_59				
B3_60				
B3_61				
B3_62				
B3_63				
B3_64				
B3_65				
B3_66				
B3_67				
B3_68				

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A19 Appendix C Board #1 Connections SOP A19 CA-1000 – v 2.0	04/20/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A20
PC Set Up

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara Clough	04/14/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	A20 Appendix A
		A20 Appendix B

1. PURPOSE

The purpose of this document is to outline the procedures set up the Personal Computer (PC) used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel setting up the PC for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

Required Hardware				
Item	**Qty**	**Vendor**	**Part #**	**Picture**
Dell Precision 490 Mini-Tower dual-core Xenon processor 5160 3.00 GHz, 4 MB L2 Cache, 1333MHz **Note**: PC specs are given in Appendix A	1	Dell		
PCI-6229 Multifxn DAQ board, 32 Anln, 4AnOut, 48 DIO, 2CT	1	NI	PCI-6229	
1394 3PT PCI Card (A0781561)	1	SIIG, Inc.	NN-440012-S8	
1394a Controller Card for Dell Precision 490	1	Dell		

Required Software	Note
CMU Driver (Version: 6.4.4.128)	
NI-DAQ board driver	This driver will not be needed if the full version of Labview is installed
USB to Serial driver	
Video Graphic driver for ATI FireGL V7200	If necessary
RadBuilder license	Only if using RadBuilder and not XIP

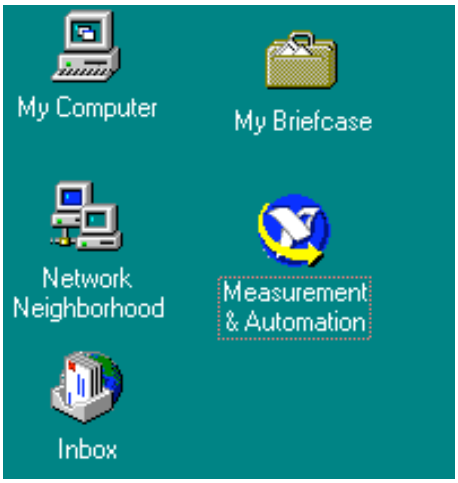
External Cables	Qty	Vendor	Part #	Description
Extended Performance Shielded Cable for M Serioes DAQ board, 5.0 m	2	National Instrument	SCH68-68-EPM	These two cables connect the PCI-6229 DAQ board to the CA-1000 box
Gray Firewire Cable	2	Hamamatsu	A8609-04	Connects ORCA control box to 3-port firewire card in the PC
20' IEEE-1394 FireWire, 6-pin male-male	1	Monster Cable	125003	Connects Color camera (in the head) to the 2-port firewire card in the PC
Ethernet/Network cable-Premium Category 6 Patch Cable, RJ45/RJ45, 3.0 ft	1	L-com	TRD695BL-3	Connects PC to Cart Entry panel
DVI-D Dual link Male/Male w/ Ferrites, 3.0 ft	2	L-com	CTLDVI-DL-MM-3	Connects PC to DVI-splitter box
USB cable	1			Connects PC USB port to USB-to-4 port Serial box

6. PROCEDURES

Step 1. Component Installation	
A. Turn off and unplug the computer, then open the computer.	
B. Install the PCI-6229 DAQ board in one open PCI slot.	
C. Install the 2-port firewire card in one open PCI slot.	
D. Install the 3-port firewire card in one open PCI slot **Note:** there is no preference as to which slot to choose for each card.	
E. Plug in and start the computer.	
F. Install all the Required Software (follow instructions for each software and restart the computer as many times as necessary). 1) Installing the CMU driver for the IEEE-1394 cameras 2) Installing the NI-DAQ board driver 3) Installing the CMU driver for the IEEE-1394 cameras	
G. Install the RadBuilder license (if necessary)	
NOTE: The computer MAC (Media Access Control) address is needed to receive the RadBuilder license file from Siemens.	
H. Install Siemens FLARE software as follows: 1) Copy only the "\bin" folder of RadBuilder on the target computer. 2) Copy "FLARE" executable file ("RadLiveCamera.exe") on the "\bin" folder. 3) Copy "RadBuilder" license file (RadLicense.ini") for the target computer on the "\bin" folder.	
Note: One RadBuilder license file is needed for the target computer.	

I. Add the following two environment variables (if not added) on the computer. 1) Variable Name: IVT_CONFIG_FILE Variable Value: [the "\bin" path in step H1]\bin\Ivt.ini 2) Variable Name: RAD_LICENSE_FILE Variable Value: [the "\bin" path in step H1]\bin\RadLicense.ini To set the environment variables do the following: 1) Click on "Start" tab. 2) Click on "Control Panel." 3) Once open find "System" icon and click to open. 4) The "System Properties" Dialog box will open. 5) Select the "Advanced" tab. 6) At the bottom of the page, select and open "Environmental Variables." 7) Under "User variables" click New. A small dialog opens, use the values given in I1 (above) to create the variable. 8) Repeat step 7 for variable I2 above.	
J. Create a shortcut for Siemens Software on the desktop.	
K. Once all external hardware is connected, displays need to be adjusted so the right monitor is showing the correct part of the software.	

Step 2. Digital Camera Ports
Note: Switching a NIR camera's firewire ports does not change the camera index (identification) number provided by the CMU or LabView driver. It is the camera head connector that drives the camera index number provided by the driver. The camera head connector has information that is directly stored in the NIR camera register.
When using the system/cameras with Siemens software, there are some restrictions as follows: • The top right NIR camera (NIR 1) should list the number 0 as camera identification. • The bottom left NIR camera (NIR 2) should list the number 1 as camera identification. • The color camera should list the number 2 as camera identification. (The driver will always automatically give the number 2 to the color camera if two NIR cameras are also connected.)
Note: The only way the user will know the driver gave the correct identification numbers to the NIR cameras is after running the software, at which point the user will see if the NIR camera images are displayed inversely, i.e. NIR 1 display at NIR 2 and NIR 2 at NIR 1 display, if the NIR cameras' identification are reversed. At this time the user will know which camera has 0 or 1 as identification and will have to switch the camera head connector cable. To avoid having to always do this manipulation, the very first time the system is assembled, the user should put a label on the imaging head, cable connectors, and camera controllers. There will be a feature provided with the software to resolve this retraction.

Step 3. Switching to the FLARE™ Driver and Siemens Measurement and Automation Software	
Before beginning this procedure, make sure that 1) all the camera devices are connected to the computer using their respective firewire cables, and that 2) the camera devices that have a controller need are turned on.	
A. Locate the Measurement and Automation icon (pictured) on the desktop and double click to start the program.	
B. When the program opens, click on “Devices and Interfaces.”	
C. Under “Devices and Interfaces,” click on “Legacy NI-IMAQ IEEE 1394 Devices”	
D. The following devices will be visible: • IMI-Tech IMC-80F • Cam1: HAMMATSU C4742-80-12AG V2.0 • Cam2: HAMMATSU C4742-80-12AG V1.0	
E. One at a time, right click on each camera to open a small menu/Dialog box. Select “Driver” and then select “CMU 1394 Digital Camera Device.”	
F. Click “Yes” and continue. If given the option, select “Continue Anyway.”	
G. Once the “CMU 1394 Digital Camera Device” driver has been updated for all three cameras, click “Save,” exit the software, and restart the computer. After the computer has restarted, the Siemens Measurement and Automation Software should be ready to use.	

Step 4. Using Windows XP Device Manager Software	
If the user needs to switch to the installed IEEE-1394 Cameras' CMU driver, but does not have the Measurement & Automation software installed on the computer, the Device Manager software available on the Windows XP Operating System may be used as an alternative.	
A. From the desktop menu, click on the "Start" menu and then click "Control Panel."	
B. On the "Control Panel" dialog box, double-click on "System."	
C. On the "System Properties" dialog box, select the "Hardware" tab and then click on the "Device Manager" button.	
D. From the "Device Manager" dialog box, click on the "+" sign near the "Imaging Devices" to expand the list of cameras connected to the computer.	
E. Select the camera to change the driver for and right click to open the pop-up dialog box.	
F. On the pop-up dialog box, click "Update Driver…"	
G, On the "Hardware Update Wizard" select "Yes, this time only" and click on the "Next >" button.	
H. On the next screen, select "Install from a list or specific location (Advanced)" and click on the "Next >" button.	
I. Select "Don't search. I will choose the driver to install" and then click on the "Next >" button.	
J. On the next screen, select "CMU 1394 Digital Camera Device" from the list and then click on the "Next >" button.	
K. On the "Hardware Installation," click on the "Continue Anyway" button.	
L. Click the "Finish" button on the next screen showing the completion of the hardware update.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A20 PC Set Up	04/14/2009	Barbara Clough
V 1.0	Modified Record	Edited	06/12/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A20 Appendix A
Computer Specifications

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/20/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A20 PC Set Up v 2.0	None	None

Flare System Configuration	**PC # 1 (Currently at SCR)**	**PC#2 (Currently in the OR)**	**PC#3 (For Clinical Use)**
1. Hardware Specifications			
PC Model:			
Service tag	B3RQWB1	GDoZCD1	6849RB1
i. System Model	Dell Precision 490 **Mini-Tower** Dual Core Xeon Proc 5060 3.20GHz, 2X 2MB L2 Cache 1066MHz	Dell Precision 490 **Mini-Tower** Dual Core Xeon Proc 5060 3.20GHz, 2X 2MB L2 Cache 1066MHz	Dell Precision 490 **Mini-Tower**, Dual Core Xeon Proc 5160 3.00GHz 4MB L2 Cache, 1333MHz,Energy Smart
ii. CPU Speed	3.20GHz	3.20GHz	3.00GHz
iii. CPU Model	Intel Xeon(TM)	Intel Xeon(TM)	Dual Core Xeon Proc 5160
iv. RAM	2GB, DDR2 ECC SDRAM Memory 533MHz, 2X1GB	2GB, DDR2 ECC SDRAM Memory 533MHz, 2X1GB	2GB, DDR2 ECC SDRAM Memory 667MHz
v. Virtual Memory	2.00GB	2.00GB	
vi. Hard Drive: model and speed	2x80GB SATA 3.0 Gb/s, 7200RPM, 8MB Dual Burst Cache	2x80GB SATA 3.0 Gb/s, 7200RPM, 8MB Dual Burst Cache	2x80GB SATA 3.0Gb/s, 7200RPM NCQHardDrive with 8MB DataBurst

Video Graphics Card:			
i. Model Number	ATI FireGL V7200 **dual VGA or DVI**	ATI FireGL V7200 **dual VGA or DVI**	ATI Fire GL V7200 **dual VGA or DVI**
ii. Memory	256MB	256MB	
iii. Driver Version	8.391.2.1100	8.223.0.0	

COMs Port Configuration			
i. COM4 (on USB-to-4serial port)	connect to motor drive controlling the Focus		

ii. COM5 (on USB-to-4serial port)	connect to motor drive controlling the Zoom		
iii. COM6 (on USB-to-4serial port)	uController		

Display Resolution:			
i. Displays resolution	1600x1200		
ii. Color Quality	Highest (32bit)		

2. Software Specifications			
Windows OS:			
i. OS version:	Windows XP Professional (Version 2002)		
ii. Service Pack version	5.1.2600 Service Pack 2 Build 2600		

3. Chassis	**Mini-tower orientation** with feet: (WxHxD) 6.73" x 17.64" x 18.54"; 17.1 cm x 44.8 cm x 47.1 cm (maximum including badge) Two internal 3.5" HDD bays; Two external 5.25" optical bays, one of which can accommodate a third HDD in mini-tower orientation. One external 3.5" flex bay for floppy or media card reader, one of which can accommodate a third HDD in desktop orientation; One PCI-e x16 graphics slot, Two PCI-e x8 slots wired as x4, Two PCI-X 64bit/100MHz slots with support for 3.3v or universal cards, One PCI 32bit/33Mhz slot; 750 watts Power Factor Correcting (PFC) power supply

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A20 Appendix A Computer Specifications for SOP A20 PC Set Up – v 2.0	04/20/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A20 Appendix B
Software Specifications

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: David Burrington	04/20/2012		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
SOP A20 PC Set Up v 2.0	None	None

Windows OS	
Version:	Windows XP Professional (Version 2002)
Service Pack Version:	5.1.2600 Service Pack 2 Build 2600

CMU Camera Driver	
Driver Provider:	Carnegie Mellon University (CMU 1394 Digital Camera Device)
Driver Date:	12/03/2006
Driver Version:	6.4.4.128
Using CMU demo application, verify that the CMU driver can initialize each camera properly.	Using the demo application, set the format and mode of the camera. Click “show camera”; if the correct driver is installed the corresponding display should appear.

Imaging Devices Driver	
List of the driver supporting all the cameras (under Control Panel -> System -> Hardware tab -> Device Manager)	Only CMU 1394 Digital Camera Device (for all cam devices to avoid any conflicts).

RadBuilder	
Version Number	07/25/2007
Under \RadBuilderDev directory (where RadBuilder is installed)	
1) \bin directory	Should be all time: exactly the same on the client’s side. (A detail of this folder will be provided.)
2) \include directory	Should be all time: exactly the same on the client’s side. (A detail of this folder will be provided.)
3) \lib directory	Should be all time: exactly the same on the client’s side. (A detail of this folder will be provided.)
4) RadBuilder License path	In the files “RadBuilder.ini” and “RadBuilderd.ini” the correct path for license file should be written at the end of each file. If RadBuilder was installed on a new computer, make sure the appropriate changes are made on these files.
RadBuilder Environment Variables (Under Control Panel -> System -> Advanced tab -> Environment Variables)	
1) In “User variables” for <computer name>	Variable Name: RAD Variable Value: C:\Program Files\RadBuilderDev
2) In “System Variables”	Variable Name: IVT_CONFIG_FILE Variable Value: C:\Program Files\RadBuilderDev\bin\Ivt.ini

BIDMC Solution (Source Code)	
\BIDMC directory hierarchy	
1) \BIDMC_src directory	Source code for the FLARE application
2) \bin directory	
3) \doc directory	Documentation files
4) \install directory	Installation files: CMU driver file, RadBuilder setup file and SVN file
5) \Interface directory	Interface source code
6) \libdaq directory	Library and includes files for the DAD board
7) \lipng directory	Library and includes files for PNG pictures
8) \network directory	Should always contain the network file: “3cam_mt.rad” and two fusions files: “fusion.gsl” and “ir.gsl”
9) \RadMultiThread directory	
Check the solution configuration properties for additional include library dependencies path (both for Release and Debug modes)	
1) Under \BIDMC_src directory, open the solution file “BIDMC_src.sln” -> Project -> BIDMC_radModules Property Pages	
1a) Under Configuration Properties -> C++: under “Additional Include Directories” check if all include directories paths are correct	“$(RAD)\include” ; ”C:\Program Files\CMU\1394Camera\include”;..\..\libpng\libpng;..\..\libpng\zlib” ; “C:\Projects\BIDMC\libdaq\DAQmx ANSI C Dev\include”
1b) Under Configuration Properties -> Linker -> General: under “Additional Library Directories” check if all include directories paths are correct	“$(RAD)\lib” ; “C:\Program Files\CMU\1394Camera\lib” ; ..\..\libpng\libpng\Release;” “C:\Projects\BIDMC\libdaq\DAQm x ANSI C Dev\lib\msvc”
1c) Under Configuration Properties ->	*On release mode:* C:\Program Files\RadBuilderDev\bin\RadBuilder.exe

Debugging : under "Command"	*On Debug mode:* C:\Program Files\RadBuilderDev\bin\RadBuilderd.exe
1d) Under Configuration Properties -> Debugging : under "Command Arguments"	*On release mode:* C:\Projects\BIDMC\network\3cam_mt.rad *On Debug mode:* C:\Projects\BIDMC\network\3cam_mt.rad

REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A20 Appendix B Computer Specifications for SOP A20 PC Set Up – v 2.0	04/20/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A21
Thermocube Pre-Installation Test

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Khaled Nasr Barbara L. Clough	05/07/2007		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None.	None	None

1. PURPOSE

The purpose of this document is to outline the procedures for coupling the Thermocube used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel performing the Thermocube pre-installation testing for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

26 ft stainless steel tubing SS-TC4-TA4-TA4-264
Cooling plate
Thermocube Type – Thermocube 400 or comparable equipment

6. PROCEDURES

Steps	
A. The 26 ft stainless tubing is coupled to the cooling plate according to Figure 1 below.	

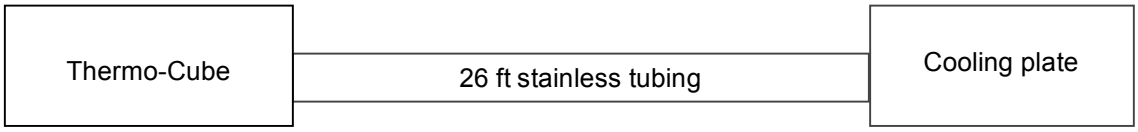


Figure 1. Schematic of coupling the thermocube to cooling plate.

B. The main elements of the tube fitting are shown in Figure 2. The fitting procedure is illustrated in Figure 3, from the movie found at http://www.swagelok.com/downloads/animations/TUBE_FITTING.HTM

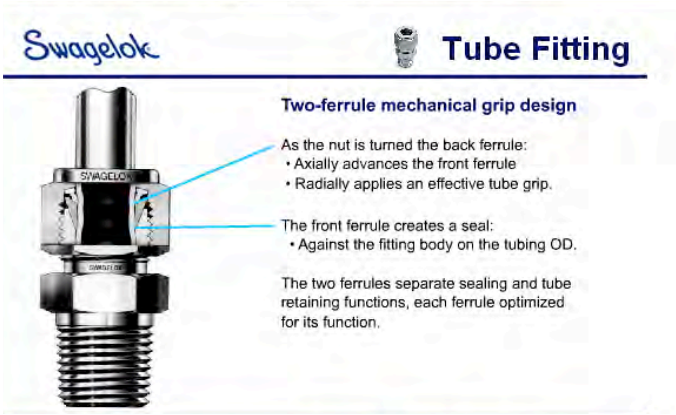


Figure 2. The main elements of the Swagelok tube fitting.

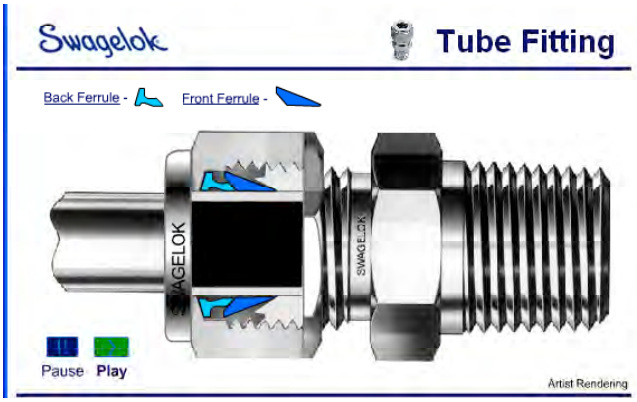


Figure 3. Swagelok tube fitting.

C. Testing the Thermocube.

- The Thermocube tank is filled with distilled water taking care to avoid overflow.
- The target temperature T_{test} ($5^{o}C$) for testing is set using buttons from the Thermocube front panel (Figure 4).
- The temperature read by the Thermocube should be compared with the temperature measured by a thermometer placed on a liquid recipient placed on the cooling plate.
- Record the targeted temperature, target and time needed to be achieved.

Figure 4. Thermocube front panel.

Acceptance Criteria

- The system Thermocube – 26 ft stainless tubing – cooling plate must present with no cooling fluid leakage.
- The target temperature read by the Thermocube should be the same ready by thermometer ± 1 degree and should be reached in less than twenty (20) minutes.

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A21 Thermocube Pre-Installation Test	05/07/2007	Khaled Nasr Barbara L. Clough
V 1.0	Modified Record	Edited	04/26/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A22
Brake Connections

Version 1.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough Alan Stockdale	06/11/2009		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	A22 Appendix A

1. PURPOSE

The purpose of this document is to outline the procedures for connecting the brakes and brake switches used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

There are no forms for this SOP.

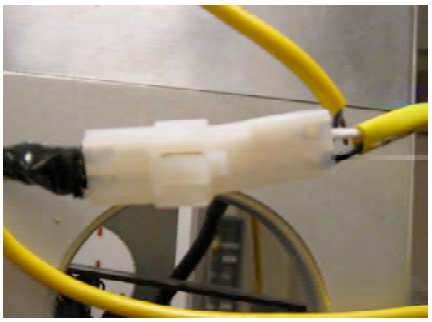
5. MATERIALS AND EQUIPMENT

The following materials will be needed for completion of this SOP.

SOP A22 Appendix A Brake Connection Schematics

Name	Manufacturer	Part #	Qty.
Diode		1N4003	1
.093” receptacle, 2 position	Molex	03-09-1028	1
.093” plug, 2 position	Molex	03-09-2028	1
Terminal, male, 14-20awg	Molex	02-09-6106	1
Terminal, female, 14-20awg	Molex	02-09-5106	1
Braking Motor cable, 3 conductor, 22AWG, 5 meters, female, single-ended	Woodhead	803000A09M050	1

6. PROCEDURES

Steps for Assembling the Connections	
A. On each brake a piece of yellow 2 conductor cable is already attached. The conductors are black and white. From the breakout panel on the head, attach the connector end of the Woodhouse cable. There are three (3) wires in this cable – blue, brown, and black. The blue will be positive and the black will be negative. Brown is not used.	
B. Cut this piece of cable so that it will comfortably reach Brake 1 at the top of the head.	
C. Cut a second piece of yellow cable that will comfortable reach from Brake 1 to Brake 2.	
D. The blue wires from these cables will share the same crimp terminal, as well as the black. Strip the ends of these wires and crimp both blue conductors into one crimp terminal. Repeat for the black conductors. Cut a piece of heat shrink tubing and feed the blue and black crimped conductors through the tubing, and then insert into the Molex plug.	
E. Strip the wires from Brake 1 and crimp the cathode side of the diode and the white conductor into the same crimp terminal.	
F. Crimp the anode end of the diode and the black conductor into another crimp terminal. Insert the white and black terminals into another piece of heat shrink tubing, and insert into the Molex receptacle so that the white will be connected to the blue, and the black to the black once the connections are made.	
G. Repeat the procedures above for all the brakes – essentially making a daisy chain connection all the way to Brake 5.	

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A22 Brake Connections	06/11/2009	Barbara L. Clough Alan Stockdale
V 1.0	Modified Record	Edited	04/26/2012	David Burrington

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A22 Appendix A
Brake Connection Schematics

Version 0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Lorissa Moffitt	10/01/2011		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
A22 Brake Connections	None.	None.

1. BRAKE AND BRAKE SWITCHES – GENERAL DIAGRAM

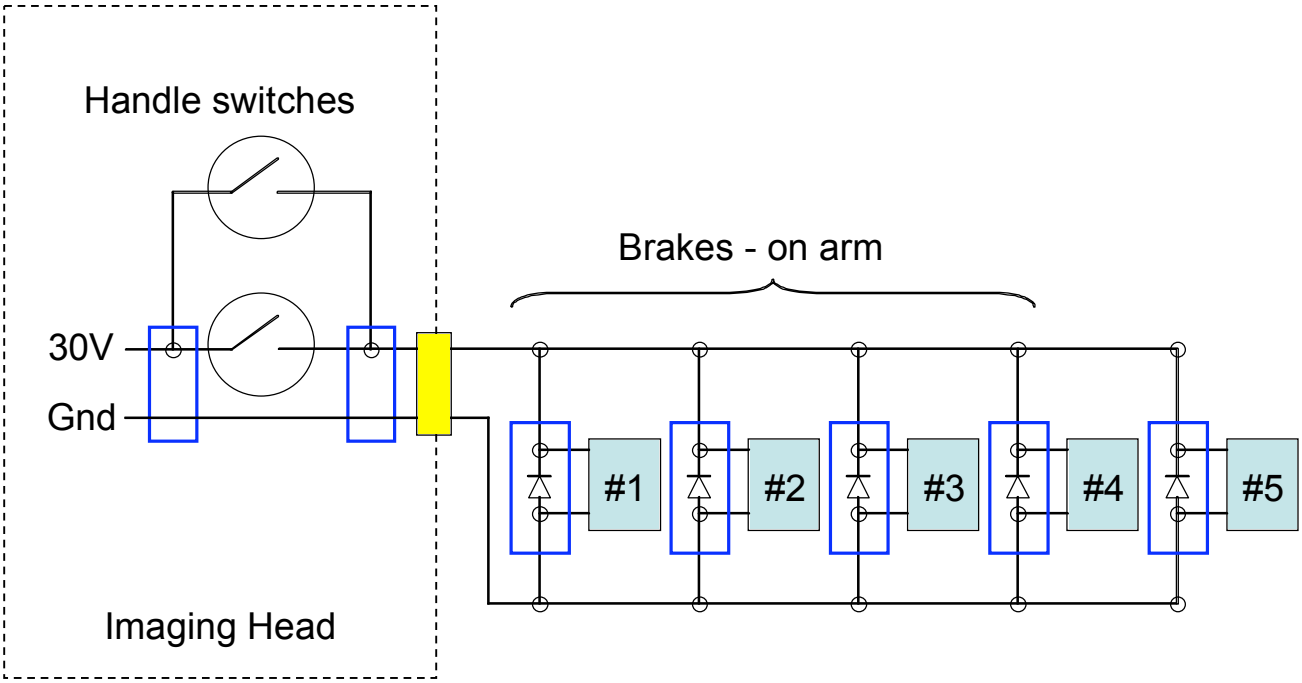


Figure 1. Brake and Brake Switches general diagram.

Symbol	Description
	Brakes 3 Wires Receptacle (for detail view, see Figure 2.)
	Molex, 2 circuits connectors, 0.093”

2. IMAGING HEAD – DETAIL DIAGRAM

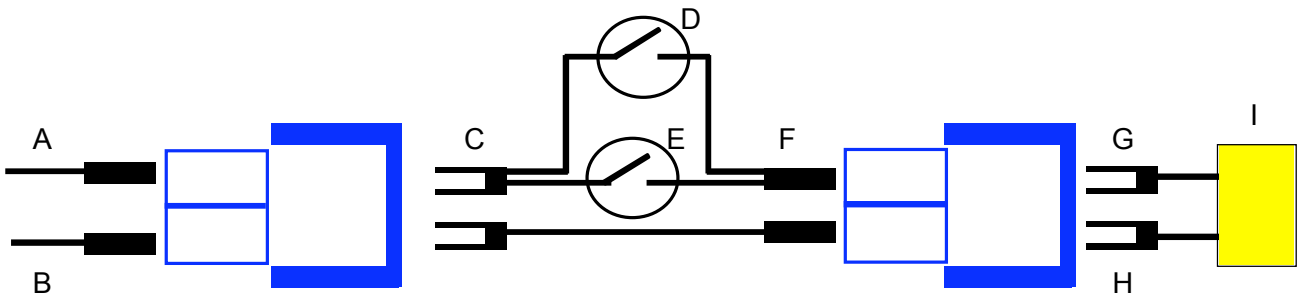
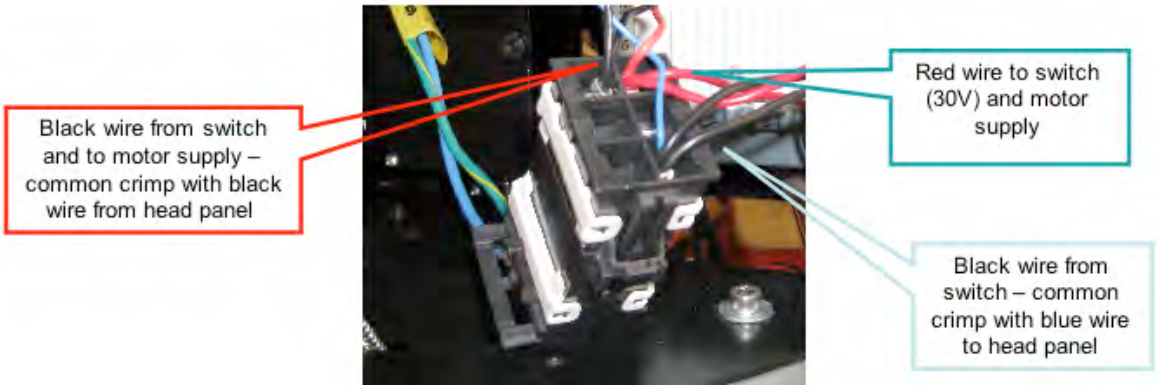


Figure 2. Brake and Brake Switches general diagram.

Symbol	Description
	Molex 2 circuits female receptacle, 0.093”
	Molex 2 circuits male header, 0.093”
	Molex female crimp connector, 0.093”
	Molex male crimp connector, 0.093”
A	30 V Line
B	30 V Ground Line
C	Both wires attached to this crimp are red.
D	Switch #1
E	Switch #2
F	Both wires attached to this crimp are black.
G	Blue wire
H	Black wire
I	Brakes 3 wires receptacle



REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created A22 Appendix A Brake Connection Schematics for SOP A22 Brake Connections.	10/01/2011	Lorissa Moffitt

Frangioni Laboratory
Center for Molecular Imaging
Beth Israel Deaconess Medical Center

Standard Operating Procedure

A23
Satellite Monitor and Stand

Version 2.0 (10/01/2011)

Approval Signatures

Printed Name	Date	Signature	Date
Author: Barbara L. Clough	08/05/2008		
Supervisor:			
Regulatory Affairs/QA:			

Associated Assembly SOPs	Associated Testing SOPS	Additional Documents
None	None	None

1. PURPOSE

The purpose of this document is to outline the procedures for assembling the Satellite Monitor and Stand used with the clinical use Fluorescence-Assisted Resection and Exploration (FLARE™) imaging system designed by the Frangioni Laboratory at Beth Israel Deaconess Medical Center (BIDMC).

2. SCOPE

This procedure applies to all personnel assembling the Satellite Monitor and Stand for the FLARE™ imaging system.

3. RESPONSIBILITIES

The Principal Investigator (PI) is responsible for adherence to protocols and standard operating procedures. These tasks are to be performed by the PI or appropriately trained personnel as designated by the PI.

4. FORMS

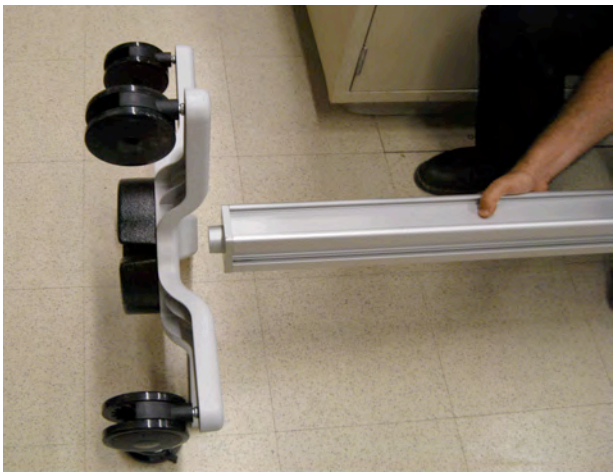
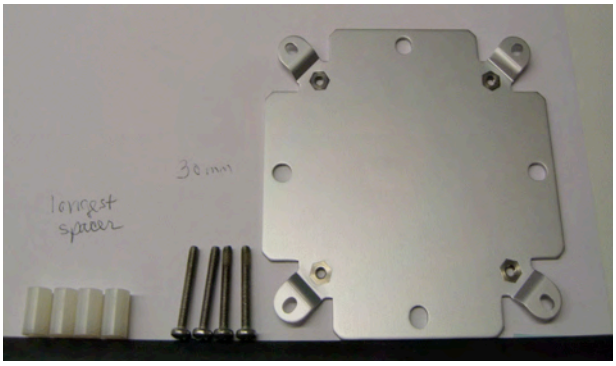
There are no forms for this SOP.

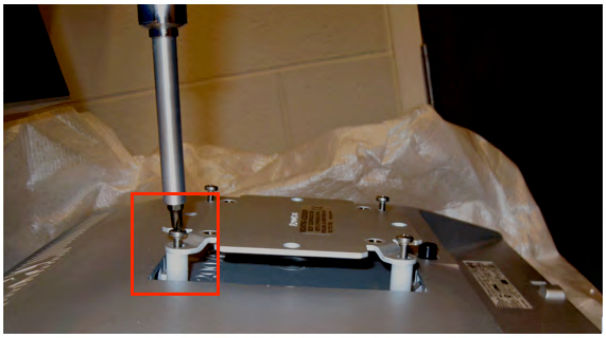
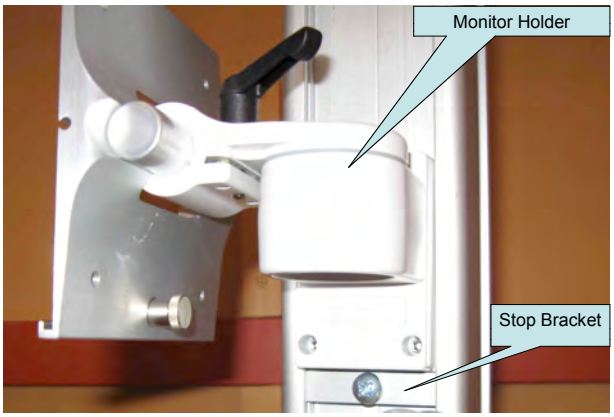
5. MATERIALS AND EQUIPMENT

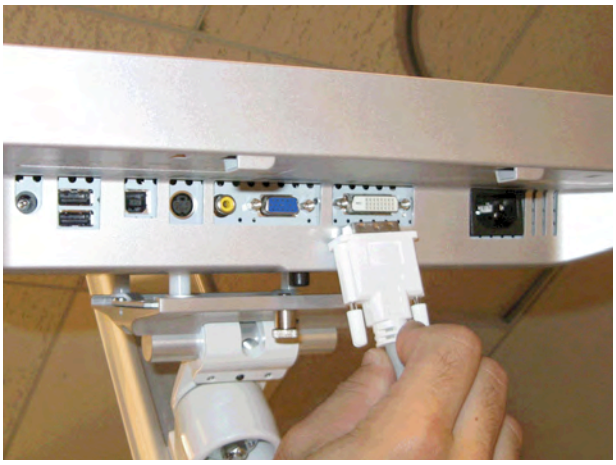
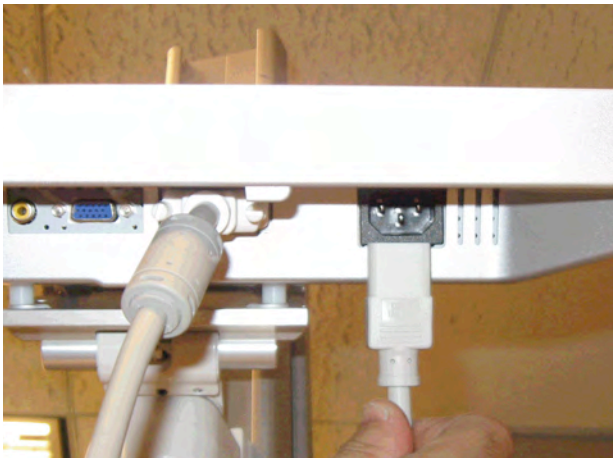
The following materials will be needed for completion of this SOP.

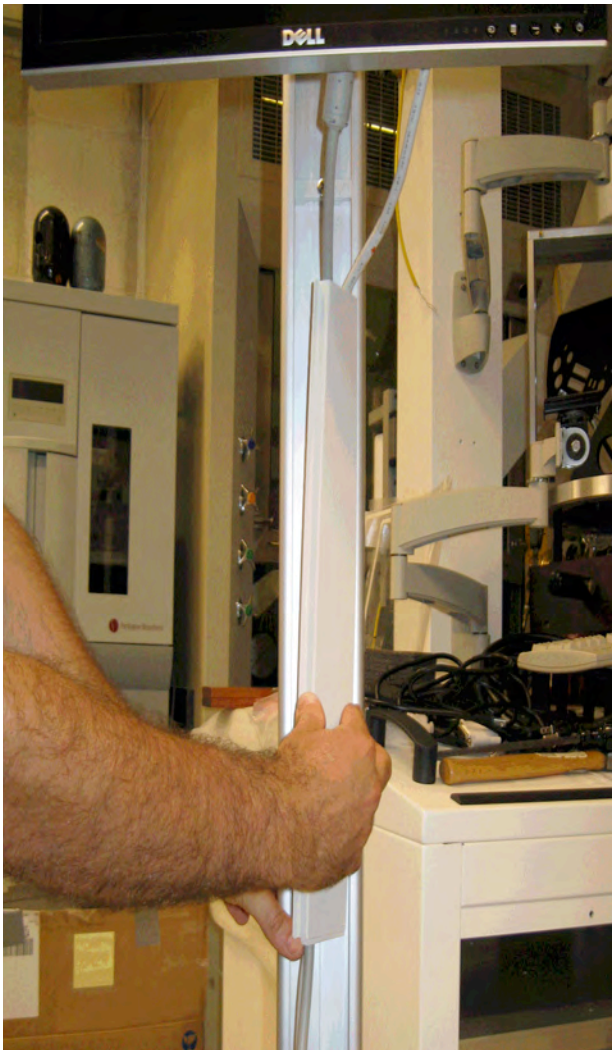
One wheeled base
One stand
One 20” monitor
Assorted screws

6. PROCEDURES

Steps	
A. Remove all items from packaging. Set the base on end as shown.	
B. The stand comes with two screws. Take out these screws and align the two holes on the bottom of the stand with the two holes on the base. Put the screws in and tighten. Turn assembled base and stand upright.	
C. Unpack and organize the following items: One 20-inch monitor Four large spacers Four 30 mm screws The metal plate comes with the monitor. There are four screws holding the plate to the monitor; these screws can be taken out and discarded – they are too short.	

D. Turn monitor face down on a padded or covered table to eliminate the possibility of scratching the screen. Insert spacer, place monitor mount on top, insert screws, and tighten.	
E. Leave monitor and return to the stand. Attach the stop bracket to the stand and tighten.	
F. Attach the monitor holder to the stand and tighten.	

G. Attach the monitor to the monitor bracket by sliding the monitor plate on to the bracket attached to the stand. Make sure that the small button pops through the monitor plate to “lock” the plate to the bracket. The monitor slides on to the monitor bracket. Slide the bracket all the way over until the button pops out.	
H. Tilt the monitor up so the cable receptacles are visible. Plug in the monitor power cable for power, and a 25 ft DVI-D male-to-male dual link cable (Sewell Direct, SW-2603-25) for the monitor. Plug in as indicated.	 

I. Feed the cables through the trough on the front of the monitor stand, and then cove the cable cover as shown. Three (3) cable covers are needed to run the length of the stand, although only the first one is shown here. Satellite stand monitor are complete.	

Note: For secure storage, a flat canvas bag (28 inch x 38 inch) with grommets (McMaster-Carr, 3985T16) is used to cover the monitor. The bag is locked into place using the grommets and a padlock with a shackle diameter of 3/16 inches (McMaster-Carr, 1176A51).

7. REVISION HISTORY

Version	Description	Reason for Revision	Date	Author
V 0	Original Record	Created SOP A23 Satellite Monitor and Stand	08/05/2008	Barbara Clough
V 1.0	Modified Record	Edited	06/01/2009	Lorissa Moffitt
V 2.0	Modified Record	Reformatted for publication	10/01/2011	Lorissa Moffitt