

Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
Prepared By: TC

Project No: DHF-05-03
Date: 9-20-05

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
I/O SIGNALS													
1	Pin 3	COLLCAN3OVF-0	Signal from Conditioning board indicating overfull condition on the canister (0= Full, 1= Not Full)	Open connection due to trace, wire, bond breakage or disconnection	Cannot detect overfull condition on canister	Canister could overflow and spill blood.	3	2	6	Sensor de-activated Normally Closed valve to shut off vacuum.	1	3	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
1a			(0= Full, 1= Not Full)	Signal Stuck High	Cannot detect overfull condition on canister	Canister could overflow and spill blood.	3	2	6	Sensor de-activated Normally Closed valve to shut off vacuum.	1	3	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
1b			(0= Full, 1= Not Full)	Signal Stuck Low	Detects overfull condition on canister perpetually	Vacuum valve is continually shut off and cannot aspirate fluid on to canister. Cannot start procedure due to lack of input.	1	2	2	System verifies that this signal is HIGH during system check. If not, system enters error condition and displays error message to user.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
1c		Pull-up resistor	(0= Full, 1= Not Full)	Open pull up	No effect	No effect	1	1	1	Mechanical Float valve on vacuum regulator assembly shuts off vacuum.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
2	Pin 5	PUMP1FBKABAD-0	Signal from Conditioning board indicating forward feedback condition from Pump1 (0= BAD, 1=	Open connection due to trace, wire, bond breakage or disconnection	Detects good forward feedback movement on pump 1 perpetually. Can falsely indicate that the	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume	1	2	2	System verifies that this signal is LOW during system check. If not, system enters error	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore,

LEGEND

S = SEVERITY SCALE
S = Severity
L = Likelihood
RF = Risk Factor
FL = Final Likelihood

1 – No injury
2 – Minor Injury
3 – Moderate Injury
4 – Serious Injury or death
5 – Multiple serious injury or death

L = LIKELIHOOD
1 – Rare
2 – Low
3 – Moderate
4 – High
5 – Very High

RF = Risk Factor (Severity x Likelihood)
1-3 Minimal Risk – No action required.
4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
10 or > Unacceptable Risk – Must be reduced before production turn over.

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			GOOD)		pump is up to speed.	and create under filled condition resulting in improper output / wash.				condition and displays error message to user.			100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
2a			(0= BAD, 1= GOOD)	Signal Stuck High	Detects good forward feedback movement on pump 1 perpetually. Can falsely indicate that the pump is up to speed.	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	1	2	2	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
2b			(0= BAD, 1= GOOD)	Signal Stuck Low	Detects bad forward feedback from forward movement on pump 1 perpetually	Pump procedure is stopped due to bad feedback signal during pump initiation. User cannot initiate / complete with procedure.	1	2	2	Detection of bad feedback signal forces error condition and displays error message.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
2c		Pull-up resistor	(0= BAD, 1= GOOD)	Open pull up	No effect	No effect	1	1	1	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
3	Pin 7	PUMP1FBKCBAD-0	Signal from Conditioning board indicating reverse feedback condition from Pump1 (0= BAD, 1= GOOD)	Open connection due to trace, wire, bond breakage or disconnection	Detects good feedback from reverse movement on pump 1 perpetually	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	1	2	2	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B

LEGEND

S = Severity	1 – No injury	L = LIKELIHOOD	1 – Rare	RF = Risk Factor (Severity x Likelihood)	1-3 Minimal Risk – No action required.
L = Likelihood	2 – Minor Injury		2 – Low		4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
RF = Risk Factor	3 – Moderate Injury		3 – Moderate		10 or > Unacceptable Risk – Must be reduced before production turn over.
FL = Final Likelihood	4 – Serious Injury or death		4 – High		
	5 – Multiple serious injury or death		5 – Very High		

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3a			(0= BAD, 1= GOOD)	Signal Stuck High	Detects good feedback from reverse movement on pump 1 perpetually	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	1	2	2	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
3b			(0= BAD, 1= GOOD)	Signal Stuck Low	Detects bad feedback from reverse movement on pump 1 perpetually	Pump procedure is stopped due to bad feedback signal. User cannot initiate / complete with procedure.	1	2	2	Pump is monitored during initiation	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
3c		Pull-up resistor	(0= BAD, 1= GOOD)	Open pull up	No effect	No effect	1	1	1	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
4	Pin 9	DOORFDBKLOCKED-0	Signal from Conditioning board indicating feedback condition of locking solenoid (0= LOCKED, 1= UNLOCKED)	Open connection due to trace, wire, bond breakage or disconnection	Detects unlocked position on lid lock solenoid perpetually	Can never initiate centrifuge operation. No processed output.	1	2	2	System unlocks bolt during procedure, verifies that lid is locked sensor is operational.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
4a			(0= LOCKED, 1= UNLOCKED)	Signal Stuck High	Detects unlocked position on lid lock solenoid perpetually	Can never initiate centrifuge operation. No processed output.	1	2	2	System unlocks bolt during procedure, verifies that lid is locked sensor is operational.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G

LEGEND

S = Severity	1 – No injury	L = LIKELIHOOD	1 – Rare	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	2 – Minor Injury		1-3	Minimal Risk – No action required.
RF = Risk Factor	3 – Moderate Injury		4-9	Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	4 – Serious Injury or death		10 or >	Unacceptable Risk – Must be reduced before production turn over.
	5 – Multiple serious injury or death			

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													PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
4b			(0= LOCKED, 1= UNLOCKED)	Signal Stuck Low	Detects locked position on lid lock solenoid perpetually	Could initiate centrifuge operation when lid is not locked.	2	2	4	System locks bolt during procedure, verifies that lid sensor is operational prior to initiation.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
4c		Pull-up resistor	(0= LOCKED, 1= UNLOCKED)	Open pull up	No effect	No effect	1	1	1	System unlocks bolt during procedure, verifies that lid is locked sensor is operational.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
5	Pin 11	P1VACUUM-0	Signal from Conditioning board indicating pressure sensor 1 detects vacuum condition (0= VACUUM, 1= NO VACUUM)	Open connection due to trace, wire, bond breakage or disconnection	Detects no vacuum condition perpetually on P1	Cannot detect when system runs out of processing saline. Cannot complete washing process	1	2	2	System check verifies operation of sensors with induced low pressure condition.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
5a			(0= VACUUM, 1= NO VACUUM)	Signal Stuck High	Detects no vacuum condition perpetually on P1	Cannot detect when system runs out of processing saline. Cannot complete washing process	1	2	2	System check verifies operation of sensors with induced low pressure condition.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
5b			(0= VACUUM, 1= NO	Signal Stuck Low	Detects vacuum	Nuisance error condition	1	3	3	System check for this	1	1	Software Requirements,

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			VACUUM)		perpetually on P1	is detected.				condition is detected and error message is displayed.			# PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
5c		Pull-up resistor	(0= VACUUM, 1= NO VACUUM)	Open pull up	No effect	No effect	1	2	2	System check verifies operation of sensors with induced low pressure condition.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
6	Pin 21	PUMP_CMD+	Positive Voltage Signal from CPLD board Controller to PUMP controller	Open connection due to trace, wire, bond breakage or disconnection	Cannot deliver pump voltage to Pump Controller. Unable to initiate pumps.	Cannot transfer fluid, cannot initiate / proceed with procedure.	1	2	2	Error condition is detected and error message is displayed.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
6a			Positive Voltage Signal from CPLD board Controller to PUMP controller	Signal Stuck High	Uncontrolled maximum Pump Drive Voltage always present	Pump runs at maximum speed, incorrect fluid transfers. Can create high pressure condition and burst fluid lines.	4	2	8	Overpressure condition is detected and procedure is stopped. Pump speed / direction sensors are monitored.	1	4	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
6b			Positive Voltage Signal from CPLD board Controller to PUMP controller	Signal Stuck Low	No Pump Drive Voltage	Cannot transfer fluid, cannot initiate / proceed with procedure.	1	2	2	Error condition is detected and error message is displayed.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone,

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													Macropore, 100-000XXX-11, Rev. B
7	Pin 23	ACMD_RET	Reference Voltage Signal (-) from CPLD board Controller to PUMP controller and Servo Controller	Open connection due to trace, wire, bond breakage or disconnection	Cannot deliver pump voltage to Pump Controller and Servo Controller	Cannot transfer fluid or centrifuge cannot initiate / proceed with procedure.	1	2	2	Error condition is detected and error message is displayed.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
7a			Reference Voltage Signal (-) from CPLD board Controller to PUMP controller and Servo Controller	Signal Stuck High	Uncontrolled Pump Drive & Servo Voltage always present	Incorrect transfer fluid or centrifuge speed, improper procedure.	1	2	2	Tachometer function on servo controller detects erroneous speed profile and enters error state	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
7b			Reference Voltage Signal (-) from CPLD board Controller to PUMP controller and Servo Controller	Signal Stuck Low	No Pump & Servo Drive Voltage	No effect, signal is always expected to be low.	1	2	2	Error condition is detected and error message is displayed.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
8	Pin 25	PUMPSEL TWO-1	Signal to select either Pump 1 or Pump 2 (0= Pump1, 1= Pump 2)	Open connection due to trace, wire, bond breakage or disconnection	Pump 1 is perpetually selected	Incorrect fluid transfer	1	2	2	System checks for pump error condition and error message is displayed.	1	1	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
8a			(0= Pump1, 1= Pump 2)	Signal Stuck High	Pump 2 is perpetually	Incorrect fluid transfer	1	2	2	System checks for pump	1	1	Software Requirements,

LEGEND

S = Severity	1 – No injury	L = LIKELIHOOD	1 – Rare	RF = Risk Factor (Severity x Likelihood)	1-3 Minimal Risk – No action required.
L = Likelihood	2 – Minor Injury		2 – Low		4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
RF = Risk Factor	3 – Moderate Injury		3 – Moderate		10 or > Unacceptable Risk – Must be reduced before production turn over.
FL = Final Likelihood	4 – Serious Injury or death		4 – High		
	5 – Multiple serious injury or death		5 – Very High		

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					selected					error condition and error message is displayed.			# PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
8b			(0= Pump1, 1= Pump 2)	Signal Stuck Low	Pump 1 is perpetually selected	Incorrect fluid transfer	1	2	2	System checks for pump error condition and error message is displayed.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
9	Pin 27	UNLOCK-1	Signal to unlock lid lock bolt (0= UNLOCK, 1= LOCK)	Open connection due to trace, wire, bond breakage or disconnection	Floating signal, undetermined lock selection.	Lock bolt never is locked. Lid is never locked. User can reach inside while centrifuge is spinning.	4	3	1 2	Lock selection with optical sensor feedback to verify actuation of bolt, error condition is entered and message is displayed.	1	4	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
9a			(0= UNLOCK, 1= LOCK)	Signal Stuck High	Lock signal is perpetually set to LOCK.	Cannot open lid to load disposable. Cannot initiate / proceed with procedure.	2	2	4	Operation of lid is required prior to initiation of process to check operation of latch / lock mechanisms.	1	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
9b			(0= UNLOCK, 1= LOCK)	Signal Stuck Low	Lock signal is perpetually set to UNLOCK.	Lock bolt never is locked. Lid is never locked. User can reach inside while centrifuge is spinning.	4	3	1 2	Lock selection with optical sensor feedback to verify actuation of bolt, error condition is entered and message is displayed.	1	4	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone,

LEGEND

S = Severity	1 – No injury	L = LIKELIHOOD	1 – Rare	RF = Risk Factor (Severity x Likelihood)	1-3 Minimal Risk – No action required.
L = Likelihood	2 – Minor Injury		2 – Low		4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
RF = Risk Factor	3 – Moderate Injury		3 – Moderate		10 or > Unacceptable Risk – Must be reduced before production turn over.
FL = Final Likelihood	4 – Serious Injury or death		4 – High		
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													Macropore, 100-000XXX-11, Rev. B
10	Pin 51	PUMPLIDSCLOSED-1	Input signal from Pre-Conditioning board to indicate lid sensors condition (0= OPEN, 1= CLOSED)	Open connection due to trace, wire, bond breakage or disconnection	Pump Lids Signal always indicates closed due to pull-up.	Pump can initiate even when the pump lids are closed resulting in improper fluid transfer. Pressure build up. User cannot initiate / proceed with procedure.	3	2	6	No mitigation is in place for this condition.	2	6	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
10a			(0= OPEN, 1= CLOSED)	Signal Stuck High	Pump Lids Signal always indicates closed.	Pump can initiate even when the pump lids are closed resulting in improper fluid transfer. User cannot process fluids.	3	2	6	No mitigation is in place for this condition.	2	6	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
10b			(0= OPEN, 1= CLOSED)	Signal Stuck Low	Pump Lids Signal always indicates open.	Pump will never initiate. User cannot process fluids.	2	2	4	Error condition is detected during system check. Message is displayed.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
11	Pin 53	PRESSUREHI-0	Input signal from Pre-Conditioning board to indicate hi pressure condition on P1 or P2 (0= HIGH PRESSURE DETECTED, 1= HIGH PRESSURE NOT DETECTED)	Open connection due to trace, wire, bond breakage or disconnection	High Pressure condition ignored perpetually due to pull-up.	High pressure condition could never be detected. Overpressure can occur resulting in burst of lines releasing fluids.	4	3	1 2	Error condition is detected during system check.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
11a			(0= HIGH PRESSURE	Signal Stuck High	High Pressure condition	High pressure condition	4	3	1	Error condition is detected	1	4	Software Requirements,

LEGEND

S = Severity	S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	1 – No injury	1 – Rare	1-3 Minimal Risk – No action required.
RF = Risk Factor	2 – Minor Injury	2 – Low	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	3 – Moderate Injury	3 – Moderate	10 or > Unacceptable Risk – Must be reduced before production turn over.
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	5 – Multiple serious injury or death	5 – Very High	

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			DETECTED, 1= HIGH PRESSURE NOT DETECTED)		ignored perpetually	could never be detected. Overpressure can occur resulting in burst of lines releasing fluids.			2	during system check.			# PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
11b			(0= HIGH PRESSURE DETECTED, 1= HIGH PRESSURE NOT DETECTED)	Signal Stuck Low	High Pressure perpetually detected	User cannot proceed / initiate process.	4	2	8	Error condition is detected during system check.	1	4	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
12	Pin 55	COLOR2BLOOD-0	Input signal from Pre-Conditioning board to indicate blood sensed on Color Sensor 2 (0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Open connection due to trace, wire, bond breakage or disconnection	Air / Saline is perpetually detected	Blood is never detected. Cannot initiate / proceed with process. Improper output.	1	2	2	No mitigation.	2	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
12a			(0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Signal Stuck High	Air / Saline is perpetually detected	Blood is never detected. Cannot initiate / proceed with process. Improper output.	1	2	2	No mitigation.	2	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
12b			(0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Signal Stuck Low	Blood is perpetually detected	Blood is perpetually detected. Improper output.	1	2	2	System checks for air / saline present in system. Error condition if blood is detected.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone,

LEGEND

S = SEVERITY SCALE
S = Severity
L = Likelihood
RF = Risk Factor
FL = Final Likelihood

1 – No injury
2 – Minor Injury
3 – Moderate Injury
4 – Serious Injury or death
5 – Multiple serious injury or death

L = LIKELIHOOD
1 – Rare
2 – Low
3 – Moderate
4 – High
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RF = Risk Factor (Severity x Likelihood)
1-3 Minimal Risk – No action required.
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Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
Prepared By: TC

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
													Macropore, 100-000XXX-11, Rev. B
13	Pin 57	COLOR1BLOOD-0	Input signal from Pre-Conditioning board to indicate blood sensed on Color Sensor 1 (0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Open connection due to trace, wire, bond breakage or disconnection	Air / Saline is perpetually detected	Blood is never detected. Cannot initiate / proceed with process. Improper output.	1	2	2	No mitigation.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
13a			(0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Signal Stuck High	Air / Saline is perpetually detected	Blood is never detected. Cannot initiate / proceed with process. Improper output.	1	2	2	No mitigation.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
13b			(0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Signal Stuck Low	Blood is perpetually detected	Blood is perpetually detected. Cannot initiate / proceed with process.	1	2	2	System checks for air / saline present in system. Error condition if blood is detected.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
14	Pin 59	COLOR3BLOOD-0	Input signal from Pre-Conditioning board to indicate blood sensed on Color Sensor 3 (0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Open connection due to trace, wire, bond breakage or disconnection	Air / Saline is perpetually detected	Blood is never detected. Cannot initiate / proceed with process. Improper output.	1	2	2	No mitigation.	2	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
14a			(0= BLOOD DETECTED,	Signal Stuck High	Air / Saline is perpetually	Blood is never detected.	1	2	2	No mitigation.	2	2	Software Requirements,

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Failure Modes and Effects Analysis

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t i a l R F	Mitigation	L	Fnl RF	Reference Documents
			1= AIR / SALINE DETECTED)		detected	Cannot initiate / proceed with process. Improper output.							# PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
14b			(0= BLOOD DETECTED, 1= AIR / SALINE DETECTED)	Signal Stuck Low	Blood is perpetually detected	Blood is perpetually detected. Cannot terminate process automatically. Improper centrifuge time.	1	2	2	System checks for air / saline present in system. Error condition if blood is detected.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
15	Pin 61	VIBRATION-0	Input signal from Pre-Conditioning board to indicate condition of vibration sensor (0= NO VIBRATION, 1= VIBRATION DETECTED)	Open connection due to trace, wire, bond breakage or disconnection	Vibration is perpetually detected	User cannot initiate / proceed with process.	1	2	2	Error condition is entered, error message is displayed.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
15a			(0= NO VIBRATION, 1= VIBRATION DETECTED)	Signal Stuck High	Vibration is perpetually detected	User cannot initiate / proceed with process.	1	2	2	Error condition is entered, error message is displayed.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
15b			(0= NO VIBRATION, 1= VIBRATION DETECTED)	Signal Stuck Low	Vibration is never detected	Vibration on centrifuge could cause mechanical failure and potentially injure user, patient or operator.	3	3	9	No mitigation.	3	9	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone,

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Failure Modes and Effects Analysis

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
													Macropore, 100-000XXX-11, Rev. B
16	Pin 63	DOORFDBKOPEN-0	Input signal from Pre-Conditioning board to indicate condition of door latch (0= OPEN, 1= CLOSED)	Open connection due to trace, wire, bond breakage or disconnection	Latch is perpetually detected closed	Cannot initiate / proceed with process. User can open without detection from system.	3	2	6	System prompt user to actuate latch, error condition is detected and message is displayed.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
16a			(0= OPEN, 1= CLOSED)	Signal Stuck High	Latch is perpetually detected closed	Cannot initiate / proceed with process. User can open without detection from system.	3	2	6	System prompt user to actuate latch, error condition is detected and message is displayed.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
16b			(0= OPEN, 1= CLOSED)	Signal Stuck Low	Latch is always detected closed	Cannot initiate / proceed with process.	1	2	2	System prompt user to actuate latch, error condition is detected and message is displayed.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
17	Pin 65	MICRODISPSET-1	Input signal from Pre-Conditioning board to detect disposable loaded (0= MACRO, 1= MICRO)	Open connection due to trace, wire, bond breakage or disconnection	MICRO is perpetually detected	Under filling of chamber can result when Macro is loaded. Improper output. Potential out of balance condition	2	2	4	System prompts user to confirm set loaded.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
17a			(0= MACRO, 1= MICRO)	Signal Stuck High	MICRO is perpetually	Under filling of chamber	2	2	4	System prompts user to	1	2	Software Requirements,

LEGEND

S = Severity	S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	1 – No injury	1 – Rare	1-3 Minimal Risk – No action required.
RF = Risk Factor	2 – Minor Injury	2 – Low	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	3 – Moderate Injury	3 – Moderate	10 or > Unacceptable Risk – Must be reduced before production turn over.
	4 – Serious Injury or death	4 – High	
	5 – Multiple serious injury or death	5 – Very High	

Failure Modes and Effects Analysis

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
					detected	can result when Macro is loaded. Improper output. Potential out of balance condition				confirm set loaded.			# PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
17b			(0= MACRO, 1= MICRO)	Signal Stuck Low	MACRO is perpetually detected	Overfilling of chamber is possible resulting in overfilling set and fluid gets sprayed inside centrifuge resulting in biohazard condition.	3	2	6	System prompts user to confirm set loaded.	1	3	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
18	Pins 67, 69, 71, 73, 75, 77, 79, 81	VO4FDBKOPEN-0 VO3FDBKOPEN-0 VO2FDBKOPEN-0 VI1FDBKOPEN-0 VI2FDBKOPEN-0 VO1FDBKOPEN-0 VI3FDBKOPEN-0 VI4FDBKOPEN-0	Input signal from valve position sensor to indicate NC valve condition (0= OPEN, 1= CLOSED)	Open connection due to trace, wire, bond breakage or disconnection	Valve is perpetually detected closed	User cannot initiate / proceed with process. No output.	2	2	4	System verifies proper operation of valve feedback enters error condition and displays error message.	1	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
18a			(0= OPEN, 1= CLOSED)	Signal Stuck High	Valve is perpetually detected closed	User cannot initiate / proceed with process. No output.	2	2	4	System verifies proper operation of valve feedback enters error condition and displays error message.	1	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
18b			(0= OPEN, 1= CLOSED)	Signal Stuck Low	Valve is perpetually detected open	User cannot initiate / proceed with process. No output. Pressure can build up in fluid lines can rupture tubing.	3	2	6	System verifies proper operation of valve feedback enters error condition and displays error message.	1	3	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G

LEGEND

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5 – Multiple serious injury or death

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Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
													PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
19	Pin 83, 85, 87, 89, 91, 93, 95, 97	VO4CMDOPEN-1 VO3CMDOPEN-1 VO2CMDOPEN-1 VO1CMDOPEN-1 VI4CMDOPEN-1 VI3CMDOPEN-1 VI2CMDOPEN-1 VI1CMDOPEN-1	Output signal from controller to set position of NC valve (0= CLOSED, 1= OPEN)	Open connection due to trace, wire, bond breakage or disconnection	Valve perpetually remains closed	User cannot initiate / proceed with process. No output. Overpressure condition.	3	2	6	System verifies proper operation of valve feedback enters error condition and displays error message.	1	3	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
19a			(0= CLOSED, 1= OPEN)	Signal Stuck High	Valve is perpetually actuated open	Incorrect fluid transfer. Improper process output.	2	2	4	System verifies proper operation of valve feedback enters error condition and displays error message.	1	2	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
19b			(0= CLOSED, 1= OPEN)	Signal Stuck Low	Valve perpetually remains closed	User cannot initiate / proceed with process. No output. Overpressure condition.	3	2	6	System verifies proper operation of valve feedback enters error condition and displays error message.	1	3	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B
20	Pin 4	CENTFDBKBAD-0	Signal from Conditioning board indicating Servo Controller Speed Fault (0= FAULT, 1= NO FAULT)	Open connection due to trace, wire, bond breakage or disconnection	Perpetually detects No Fault for Controller Speed feedback	Improper speed for centrifuge, no viable output. Hazard condition to uncontrolled centrifuge.	4	2	8	Error condition entered upon detection of speed fault, error message is displayed.	1	4	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macpore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macpore, 100-000XXX-11, Rev. B

LEGEND

S = Severity	1 – No injury	L = LIKELIHOOD	1 – Rare	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	2 – Minor Injury		1-3 Minimal Risk – No action required.	
RF = Risk Factor	3 – Moderate Injury		4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.	
FL = Final Likelihood	4 – Serious Injury or death		10 or > Unacceptable Risk – Must be reduced before production turn over.	
	5 – Multiple serious injury or death			
		5 – Very High		

Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
Prepared By: TC

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	FnI RF	Reference Documents
20a			(0= FAULT, 1= NO FAULT)	Signal Stuck High	Perpetually detects No Fault for Controller Speed feedback	Improper speed for centrifuge, no viable output. Hazard condition to uncontrolled centrifuge.	4	2	8	Error condition entered upon detection of speed fault, error message is displayed.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
20b			(0= FAULT, 1= NO FAULT)	Signal Stuck Low	Perpetually detects Controller Speed Fault	User cannot initiate / proceed with process. No output.	2	2	4	System checks for this signal to HIGH, enters error condition and displays error message.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
20c		Pull-up resistor	(0= FAULT, 1= NO FAULT)	Open pull up	Perpetually detects No Fault for Controller Speed feedback due to internal pull-up	Improper speed for centrifuge, no viable output. Hazard condition to uncontrolled centrifuge.	4	2	8	Error condition entered upon detection of speed fault, error message is displayed.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
21	Pin 6	CENTEXFAULT-0	Signal from Conditioning board indicating Servo Controller External Fault (0= FAULT, 1= NO FAULT)	Open connection due to trace, wire, bond breakage or disconnection	Never detects External Controller Fault	System can proceed with fault condition present on the servo controller.	4	2	8	Servo Controller detects discrepancy and shuts off power to servo and servo stops.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
21a			(0= FAULT, 1= NO FAULT)	Signal Stuck High	Never detects External Controller Fault	System can proceed with fault condition present on the servo controller.	4	2	8	Servo Controller detects discrepancy and shuts off power to servo and servo stops.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G

LEGEND

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Failure Modes and Effects Analysis

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Prepared By: TC

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
													PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
21b			(0= FAULT, 1= NO FAULT)	Signal Stuck Low	Detects External Controller Fault perpetually	Cannot initiate / proceed with process, no output.	1	2	2	System checks for external fault signal to be high, issue error condition upon detection of fault signal being LOW.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
21c		Pull-up resistor	(0= FAULT, 1= NO FAULT)	Open pull up	No effect	No effect	1	2	2	System checks for external fault signal to be high, issue error condition upon detection of fault signal being LOW.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
22	Pin 8	PUMP2FDBKBAD-0	Signal from Conditioning board indicating pump movement (0= BAD, 1= GOOD)	Open connection due to trace, wire, bond breakage or disconnection	Detects good pump 2 feedback voltage perpetually	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	1	2	2	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
22a			(0= BAD, 1= GOOD)	Signal Stuck High	Detects good pump 2 feedback voltage perpetually	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	1	2	2	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
22b			(0= BAD, 1= GOOD)	Signal Stuck Low	Perpetually detects bad	Pump procedure is	2	2	4	Enter error condition and	1	2	Software Requirements,

LEGEND

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L = Likelihood	2 – Minor Injury		2 – Low	1-3 Minimal Risk – No action required.
RF = Risk Factor	3 – Moderate Injury		3 – Moderate	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	4 – Serious Injury or death		4 – High	10 or > Unacceptable Risk – Must be reduced before production turn over.
	5 – Multiple serious injury or death		5 – Very High	

Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
Prepared By: TC

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fn l R F	Reference Documents
					pump 2 EMF voltage	stopped due to bad feedback signal.				displays error message.			# PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
22c		Pull-up resistor	(0= BAD, 1= GOOD)	Open pull up	Detects good pump 2 feedback voltage perpetually, due to internal pull-up.	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	1	2	2	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
23	Pin 10	COLLCAN2FULL-0	Signal from Conditioning board indicating minimum starting liquid sensed on the canister (0= Full, 1= Not Full)	Open connection due to trace, wire, bond breakage or disconnection	Perpetually indicates Not Full condition	Never sees fluid on the canister, user cannot initiate / proceed.	2	2	4	System does not detect fluid on the canister; user can initiate process by pressing NEXT.	1	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
23a			(0= Full, 1= Not Full)	Signal Stuck High	Perpetually indicates Not Full condition	Never sees fluid on the canister, user cannot initiate / proceed.	2	2	4	System does not detect fluid on the canister; user can initiate process by pressing NEXT.	1	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
23b			(0= Full, 1= Not Full)	Signal Stuck Low	Perpetually indicates Full condition	Start condition can be falsely indicated, system can begin to pump / process fluid.	2	2	4	System checks that this is HIGH, enters error condition and displays error message.	1	2	Software Requirements, # PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone,

LEGEND

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Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
Prepared By: TC

Project No: DHF-05-03
Date: 9-20-05

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
													Macropore, 100-000XXX-11, Rev. B
23c		Pull-up resistor	(0= Full, 1= Not Full)	Open pull up	Perpetually indicates Not Full condition, due to internal pull-up.	Never sees fluid on the canister, user cannot initiate / proceed.	2	2	4	System does not detect fluid on the canister; user can initiate process by pressing NEXT.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24	Pin 12	P2VACUUM-0	Signal from Conditioning board indicating pressure sensor 2 detects vacuum condition (0= VACUUM, 1= NO VACUUM)	Open connection due to trace, wire, bond breakage or disconnection	Perpetually detects no vacuum on P2	Cannot detect when system runs out of processing saline. Cannot complete washing process	1	2	2	System check verifies operation of sensors with induced low pressure condition.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24a			(0= VACUUM, 1= NO VACUUM)	Signal Stuck High	Perpetually detects no vacuum on P2	Cannot detect when system runs out of processing saline. Cannot complete washing process	1	2	2	System check verifies operation of sensors with induced low pressure condition.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24b			(0= VACUUM, 1= NO VACUUM)	Signal Stuck Low	Perpetually detects vacuum on P2	Nuisance error condition is detected.	3	2	6	System check for this condition is detected and error message is displayed.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24c		Pull-up resistor	(0= VACUUM, 1= NO VACUUM)	Open pull up	Perpetually detects no vacuum on P2, due to	Cannot detect when system runs out of	1	2	2	System check verifies operation of sensors with	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B

LEGEND

S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
S = Severity	1 – No injury	1-3 Minimal Risk – No action required.
L = Likelihood	2 – Minor Injury	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
RF = Risk Factor	3 – Moderate Injury	10 or > Unacceptable Risk – Must be reduced before production turn over.
FL = Final Likelihood	4 – Serious Injury or death	
	5 – Multiple serious injury or death	
	5 – Very High	

Failure Modes and Effects Analysis

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Flt RF	Reference Documents
					internal pull-up	processing saline. Cannot complete washing process				induced low pressure condition.			PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24. aa	Pin 16	PUMP1FBKBADB-0	Signal from Conditioning board indicating slow forward feedback condition from Pump1 (0= BAD, 1= GOOD)	Open connection due to trace, wire, bond breakage or disconnection	Detects good forward feedback movement on pump 1 perpetually. Can falsely indicate that the pump is up to speed.	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	4	2	8	System verifies that this signal is LOW during system check. If not, system enters error condition and displays error message to user.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24. ab			(0= BAD, 1= GOOD)	Signal Stuck High	Detects good forward feedback movement on pump 1 perpetually. Can falsely indicate that the pump is up to speed.	Can falsely indicate that the pump is up to speed. Pump could pump incorrect fluid volume and create under filled condition resulting in improper output / wash.	4	2	8	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	4	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24. ac			(0= BAD, 1= GOOD)	Signal Stuck Low	Detects bad forward feedback from forward movement on pump 1 perpetually	Pump procedure is stopped due to bad feedback signal during pump initiation. User cannot initiate / complete with procedure.	1	2	2	Detection of bad feedback signal forces error condition and displays error message.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
24. ac		Pull-up resistor	(0= BAD, 1= GOOD)	Open pull up	No effect	No effect	1	1	1	System verifies that this signal is LOW during system check. If not, system enters condition and displays error message to user.	1	1	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-

LEGEND

S = Severity
L = Likelihood
RF = Risk Factor
FL = Final Likelihood

S = SEVERITY SCALE
1 – No injury
2 – Minor Injury
3 – Moderate Injury
4 – Serious Injury or death
5 – Multiple serious injury or death

L = LIKELIHOOD
1 – Rare
2 – Low
3 – Moderate
4 – High
5 – Very High

RF = Risk Factor (Severity x Likelihood)
1-3 Minimal Risk – No action required.
4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
10 or > Unacceptable Risk – Must be reduced before production turn over.

Failure Modes and Effects Analysis

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
													11, Rev. B
25	Pin 20	CENT_CMD+	Positive Voltage Signal from CPLD board Controller to Centrifuge controller	Open connection due to trace, wire, bond breakage or disconnection	Cannot deliver centrifuge voltage to Centrifuge Controller	Centrifuge cannot initiate due to loss of voltage.	2	2	4	Centrifuge controller checks for speed profile and enters error condition and error message display.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
25a			Positive Voltage Signal from CPLD board Controller to Centrifuge controller	Signal Stuck High	Uncontrolled Centrifuge Drive Voltage perpetually present	Centrifuge spins out of control.	3	2	6	Centrifuge controller checks for speed profile and enters error condition and error message display.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
25b			Positive Voltage Signal from CPLD board Controller to Centrifuge controller	Signal Stuck Low	No Centrifuge Drive Voltage	Centrifuge cannot initiate due to loss of voltage.	2	2	4	Centrifuge controller checks for speed profile and enters error condition and error message display.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
26	Pin 26	PUMPDIRREV-1	Signal to select direction for Pump 1 (0= REVERSE, 1= FORWARD)	Open connection due to trace, wire, bond breakage or disconnection	Undefined direction selection for pump 1	Cannot initiate. Reverse direction pump perpetually selected. Unable to initiate / proceed with process. High pressure condition on fluid lines.	3	2	6	System verifies direction desired, enters error condition and error message is displayed	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
26a			(0= REVERSE, 1= FORWARD)	Signal Stuck High	Forward direction for Pump 1 is perpetually selected	Forward direction pump perpetually selected. Unable to initiate /	3	2	6	System verifies direction desired, enters error condition and error	1	3	Software Requirements, #_____ PCB, Daughter, CPLD,

LEGEND

S = Severity	1 – No injury	L = LIKELIHOOD	1 – Rare	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	2 – Minor Injury		2 – Low	1-3 Minimal Risk – No action required.
RF = Risk Factor	3 – Moderate Injury		3 – Moderate	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	4 – Serious Injury or death		4 – High	10 or > Unacceptable Risk – Must be reduced before production turn over.
	5 – Multiple serious injury or death		5 – Very High	

Failure Modes and Effects Analysis

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Prepared By: TC

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	FnI RF	Reference Documents
						proceed with process. High pressure condition on fluid lines.				message is displayed			Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
26b			(0= REVERSE, 1= FORWARD)	Signal Stuck Low	Reverse direction for Pump 1 is perpetually selected	Reverse direction pump perpetually selected. Unable to initiate / proceed with process. High pressure condition on fluid lines.	3	2	6	System verifies direction desired, enters error condition and error message is displayed	1	3	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
27	Pin 28	AGITATEMOTOR-1	Signal to activate agitator motor (0= NOT ENABLED, 1= ENABLED)	Open connection due to trace, wire, bond breakage or disconnection	Agitator is never enabled	Reverse direction pump perpetually selected. Unable to initiate / proceed with process. Improper output.	2	2	4	Cannot detect condition. No mitigation	2	4	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
27a			(0= NOT ENABLED, 1= ENABLED)	Signal Stuck High	Agitator is perpetually enabled	Perpetual agitation of canister, user nuisance.	2	2	4	Cannot detect condition. No mitigation	2	4	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
27b			(0= NOT ENABLED, 1= ENABLED)	Signal Stuck Low	Agitator is never enabled	Cannot agitate fluid canister, improper processing of fluids.	2	2	4	Cannot detect condition. No mitigation	2	4	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B

LEGEND

S = Severity	S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	1 – No injury	1 – Rare	1-3 Minimal Risk – No action required.
RF = Risk Factor	2 – Minor Injury	2 – Low	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	3 – Moderate Injury	3 – Moderate	10 or > Unacceptable Risk – Must be reduced before production turn over.
	4 – Serious Injury or death	4 – High	
	5 – Multiple serious injury or death	5 – Very High	

Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
28	Pin 30	LOCKSOLCMD-1	Signal to activate lock enable relay (0= NOT ENABLED, 1= ENABLED)	Open connection due to trace, wire, bond breakage or disconnection	Lock Solenoid is never enabled	Cannot initiate / proceed with procedure. User can open lid while centrifuge is running.	3	2	6	System verifies actuation of bolt against the state condition desired, detection of activation is confirmed prior to activation of centrifuge. Error condition is entered and error message is display.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
28a			(0= NOT ENABLED, 1= ENABLED)	Signal Stuck High	Lock Solenoid is perpetually enabled	Cannot initiate / proceed with procedure. Cannot open lid to load disposable set.	3	2	6	System verifies actuation of bolt against the state condition desired, detection of activation is confirmed prior to activation of centrifuge. Error condition is entered and error message is display.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
28b			(0= NOT ENABLED, 1= ENABLED)	Signal Stuck Low	Lock Solenoid is never enabled	Cannot initiate / proceed with procedure. User can open lid while centrifuge is running.	3	2	6	System verifies actuation of bolt against the state condition desired, detection of activation is confirmed prior to activation of centrifuge. Error condition is entered and error message is display.	1	3	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
29	Pin 32	CENTENABLE-1	Signal to activate centrifuge controller (0= NOT ENABLED, 1= ENABLED)	Open connection due to trace, wire, bond breakage or disconnection	Centrifuge Controller is never enabled	Cannot initiate / proceed with procedure, no final output.	2	2	4	System verifies speed profile against command. Enters error condition and error message is displayed.	1	2	Software Requirements, #_____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
29a			(0= NOT ENABLED, 1= ENABLED)	Signal Stuck High	Centrifuge Controller is perpetually enabled	Centrifuge is perpetually enabled. Could operate prematurely.	4	2	8	Needs speed voltage command to initiate. Needs to satisfy solenoid bolt	1	4	Software Requirements, #_____ PCB, Daughter, CPLD,

LEGEND

S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
S = Severity	1 – No injury	1-3 Minimal Risk – No action required.
L = Likelihood	2 – Minor Injury	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
RF = Risk Factor	3 – Moderate Injury	10 or > Unacceptable Risk – Must be reduced before production turn over.
FL = Final Likelihood	4 – Serious Injury or death	
	5 – Multiple serious injury or death	
	5 – Very High	

Failure Modes and Effects Analysis

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Seq #	Ref #	Component	Function	Failure Mode or Defect	Local Effect of Failure	Potential System Effect of Failure	S	L	I n i t R F	Mitigation	L	Fnl RF	Reference Documents
										activation, door latch sensor, normally open door latch mechanical limit switch to activate.			Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B
29b			(0= NOT ENABLED, 1= ENABLED)	Signal Stuck Low	Centrifuge Controller is never enabled	Cannot initiate / proceed with procedure, no final output.	2	2	4	System verifies speed profile against command. Enters error condition and error message is displayed.	2	4	Software Requirements, # _____ PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B

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LEGEND

S = Severity	S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	1 – No injury	1 – Rare	1-3 Minimal Risk – No action required.
RF = Risk Factor	2 – Minor Injury	2 – Low	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	3 – Moderate Injury	3 – Moderate	10 or > Unacceptable Risk – Must be reduced before production turn over.
	4 – Serious Injury or death	4 – High	
	5 – Multiple serious injury or death	5 – Very High	

Failure Modes and Effects Analysis

Project: Celution Clinical FMEA, Firmware
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Notes:

Revision Notes: Rev JM01: 03/18/05

Firmware FMEA

Rev X01

Author: Jose Moya

Schematics:

PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. G

PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B

Notes:

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Revision Notes: Rev JM02: 08/10/05

Firmware FMEA

Rev X02

Author: Jose Moya

Schematics:

PCB, Daughter, CPLD, Brimstone, Macropore, 100-000417-11, Rev. H2

PCB, FPGA, Brimstone, Macropore, 100-000XXX-11, Rev. B

Notes: Added Item #24.a – To capture pump1 forward slow pump check. (JM)

3 Revision Notes: Rev JM03: 08/11/05

Rev X03

Author: Steve Kreinick

Notes: Added sequence numbers for each line with a risk factor. No previously assigned sequence numbers were changed except for line 24.a changed to 24.aa. Other lines were assigned identification with the last number assigned and an alphabetic (a, b, c, etc.) appended to the number (e.g. line following 1 is 1a). Lines following line 24.a became 24.aa, 24.ab, etc.

LEGEND			
S = Severity	S = SEVERITY SCALE	L = LIKELIHOOD	RF = Risk Factor (Severity x Likelihood)
L = Likelihood	1 – No injury	1 – Rare	1-3 Minimal Risk – No action required.
RF = Risk Factor	2 – Minor Injury	2 – Low	4-9 Acceptable Risk – Reasonable effort must be taken to control or detect.
FL = Final Likelihood	3 – Moderate Injury	3 – Moderate	10 or > Unacceptable Risk – Must be reduced before production turn over.
	4 – Serious Injury or death	4 – High	
	5 – Multiple serious injury or death	5 – Very High	