Design Inputs for: Device for the Controlled Reduction of Pediatric Intussusception

	Category	Parameter	Comment	Functional	Performance	Constraint	Physician	Nurse	Patient	Hospital	other	Metric	Critical	Need	Want	Reference	Test	Analysis	Demonstration	Inspection	Verification Description
	Product Requirements						User						Rating				Method of Verification				
A1	Pressure Regulation	pressure generation range	how much pressure do we need to generate in system	■			■		■			[20 mmHg, >=240 mmHg)		■		standard procedure used today goes to 120mmHg, this is double; (Shiels, 1993)	■	■			hook system up to gauge pressure indicator and read max pressure capable of being generated
A2		pressure delivery error	how much fluctuation?		■						■	estimate: +/- 10 mmHg	■			interviews suggest that fluctuations are large (as high as 100 mmHg). We hypothesize that smaller fluctuations will lead to better outcomes. This will require post prototype construction testing	■	■			hook system up to gauge pressure indicator and read error at various pressure settings
A3		pressure cut-off	what causes perforation? mechanical blowout valve; this is the worst case scenario; there should be 2 pressure safety systems in place before this safety feature will be reached	■			■		■			estimate: 500 mmHg		■		this will be a mechanical pressure blow out, which should only ever kick in if there is a failure mode. Shiels 1993 suggests that pressure should be <270 mmHg, so we increase the value for system failure	■	■			intentionally over-pressure system. Insure that system dumps pressure
B1	Rectal Device Interface	pressure retention in intestine	must be capable of holding/sealing against a pressure in intestine such that our flow rate can maintain pressure	■				■				should seal to 140 mmHg	■			standard procedure used today goes to 120mmHg, this adds a slight safety factor for spikes due to coughing, etc.. Some leakage above that pressure is acceptable; (Shiels, 1995), (Shiels, 1993), (Kaiser, 2007)	■				ensure that pressure is held in test bed intestine (ASTM D1456 - rubber elongation)
B2		enema tip size	must be insertable into rectum of child, should come in multiple sizes to satisfy patient diversity	■		■	■	■	■			at minimum 24 French and 40 French sizes		■		tips which satisfy B2 and B3 for the full range of infant anus sizes from 0-2 years old; prior art offers 24 and 40 French sizes (Grattan-Smith, 2015; Shiels, 1991)	■		■		ensure that tip can be inserted into test bed rectum and conforms to expected dimension
B3		enema tip/catheter slip-out pressure	how much pressure can be applied prior to tip/catheter slip out	■				■				500 mmHg	■			standard 140 mmHg + significant safety factor for tugging on line, child movement, Valsalva maneuver, etc... will require additional testing post prototype fabrication to determine exact value necessary (Shiels, 1995; Shiels, 1991; Mahaffey, 2015)	■				pressurize test bed rectum and ensure that tip stays inserted without user intervention
B4		enema tip insertion length	must be capable of being inserted at least 3 inches	■				■	■			>3 inches		■		current insertion length is generally 3 inches or less (Grattan-Smith, 2015; Mahaffey, 2015)	■	■			measure insertable length
C1	Physical Embodiment	storage and portability	must be capable of being stored and easily moved			■		■		■		weight is comfortable for transport by nurses (<10lbs); size is no more than prior art case (11inx9inx4in)			■	must be easy to use and fit in the same space as prior art. Interview with Grattan-Smith and visit to hospital allowed physical contact with Shiels device case (Grattan-Smith, 2015; Shiels, 1995)	■	■	■		will ensure size and weight are no larger than prior art case; will survey nurses for comfort level moving device
C2		compatiblity with non-specified tips	connectors out of pressure control system should be industry standard	■		■		■		■		luer lock compatible		■		ISO 594 (luer-lock)	■	■		■	inspection to ISO specifications
C3		visual intimidation	should minimize fear and intimidation		■		■	■	■			by survey would person (patient parent, physician, nurse) be less comfortable than with the predicate device			■	(Grattan-Smith, 2015; Mahaffey, 2015)			■		survey
E1	Environmental	environmental impact	should minimize impact on the environment			■				■	■	conform to ISO 14040 and ISO 14044 (Envirenmental Managment / Lifecycle analysis)			■	ISO 14040 and ISO 14044 (Envirenmental Managment / Lifecycle analysis)		■			process and design review
F1	Sterility	aseptic catheter/enema tip and tube	enema tip and tube should be clean			■			■	■		conform to ISO 13408 (asptic processing of healthcare products)		■		ISO 13408 (asptic processing of healthcare products)	■			■	bioburden, visual inspection
F2		flow back of liquid from patient	no fluid should return from the patient into the device with a pressure gradient up to 500 mmHg			■				■		zero flow of liquid water from patient into device at A3 pressure (500 mmHg)		■		dirty fluid is exiting the child, this must not be passed into the device and onto the next patient (Mahaffey, 2015)	■				will verify by colored water liquid and vapor being pushed through filter mechanism at A3 pressure
G1	Performance	reduction time	should be equivalent or better to current device when used on test bed		■		■	■	■	■		time to reduction of intussusception on device less than or equal to prior art when compared on our test bed		■		device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		have a trained physician perform reduction on test bed using existing device and new device compare time to successful reductions
G2		subjectively preferred by physicians	by survey of physicians, use is preferred by physicians on test bed		■		■					by survey physicians statistically prefer our device to the prior art when compared on a test bed	■			device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		user trial/survey
G3		subjectively preferred by nurses	by survey of nurses, use is preferred by nurses on test bed		■			■				by survey nurses statistically prefer our device to the prior art when compared on a test bed	■			device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		user trial/survey
G4		reduction rate	should have a higher rate of successful reduction than prior art		■		■	■	■	■		should have a higher rate of successful reduction than prior art		■		device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)			■		have a trained physician perform reduction on test bed using existing device and new device compare number of successful reductions
H1	Safety	perforation prevelance	should not lead to increased perforations compared to current device; ideally would notify if a perforation does occur		■		■		■	■		mathematically, pressure should be delivered in a more controlled fashion; tests on test bed should show no increase in perforations when compared to previous art.		■		device must be better than the prior art; data will be comparative on test bed (Shiels, 1992)	■				have a trained physician perform reduction on test bed using existing device and new device compare number of perforations. Guarantee mathematically that the pressure we deliver is in no way more likely cause perforations
H2		emergency stop	drops air pressure to zero immediately after activation	■			■			■		compliant with ISO 13850 (emergency stops) / will depressurize intestine at system max exit flow rate; kill all power to system		■		ISO 13850 (emergency stops)	■				will measure pressure output from device, time to depressurize, proper electrical state
H3		parameter indications	clear indication of set parameters and easy adjustment of said parameters		■		■					easy for a new user to understand the set parameters	■			ISO 9241 (ergonomics of human-system interaction), ISO 11581 (symbols for computer interfaces)			■		user trials
I1	Reliability/Maintenance	device health indication	comparative testing using multiple sensors to ensure accurate sensor readouts. Self test solenoids		■		■	■		■		able to detect failure of critical components	■			the device should minimize the affects of relevant failure modes		■	■		verify that system has been designed in a way as to minimized affects of relevant failure modes. Test simulated failure modes.
I3		cleanability	should be sealed against wash-down			■		■		■		must be designed for cleanability		■		current ASTM WK31799 (medical device cleanability) is in progress; will have to develop in house method	■	■			contaminate and mark device surface; wash down device; Does any fluid enter the case? Is there any damage? Is there any remaining marking or bioburden?
J1	Life Span	disposable shelf life	disposable component should be able to last for 10 years			■				■		disposable component should be able to last for 10 years		■		current BARD catheter lifespan	■	■			accelerated aging
J2		capital device lifespan	primary device should be able to last for 10 years			■				■		primary device should be able to last for 10 years		■		based on Welch Allyn hand aneroid (competitive product) warranty period	■	■			accelerated aging combined with simulated cycles
K1	Packaging	packaging should not compromise device	it should be easy to open packaging and move straight to use. Should adequately protect device from mechanical and biological attack		■		■	■				conforms to ISO 11607 (packaging for terminally sterilized medical devices), including adequate protection for the device; also allows ease of use of packaging		■		ISO 11607 (packaging for terminally sterilized medical devices)	■		■		conformance to standard for protection and user testing for ease of use.
K2		labeling should allow intuitive use	easy to read, short instructions for use (IFU)		■		■	■				conforms to ISO 15223 (symbols for medical device packaging) standard with clear labeling		■		ISO 15223 (symbols for medical device packaging)		■	■		user trials and spec conformance
L1	Interfacing Devices	electro-magnetic interference (EMI)	conforms to IEC 6060; ensure electro-magnetic interference is at a safe level; does not interfere with fluoroscopy or other relevant devices in the fluoroscopy suite			■						conforms to IEC 60601 (guide for electronic medical devices)		■		IEC 6061 (guide for electronic medical devices)	■	■			will test per standard
L2		should interface with standard hospital air source	quick disconnect to interface with 1/4 NPT and barb for tube			■	■	■		■		must interface with 1/4 NPT and soft tube (barb fitting), ISO 228 (BPT) fitting		■		ANSI B1.20.1 (NPT), ISO 228 (BPT), ASME B16 (pipe fittings)	■	■			test against specifications
M1	User Experience	intuitive use	a standard trained radiologist should be able to figure out the interface with no instruction; we will allow a basic IFU on the device		■		■	■				conforms to standard practices for interface design; by survey (physicians statistically agreeing on device being intuitive to use)	■			ISO 11581 (symbols for computer interfaces); ISO 20282 (ease of operation of everyday devices); ISO 9241 (ergonomics of human-system interaction); IEC 62366:2007 (medical device usability); AAMI-HE75 (human factors for medical devices)		■	■		user trials/standard verification
M2		glove compatibility	minimize static touch interfaces, maximize tactile feedback		■		■					all systems must function fully with gloves		■		interviews suggest that all users are fully gloved and that the environment becomes very messy with bowel fluid exiting the patient (Grattan-Smith, 2015; Mahaffey, 2015)		■	■		intelligent design and user trials
M3		status indicator	should have clear status indicator which can be read from at least 6 feet, along with more detailed data up close		■		■					indicator which can be read from at least 6 feet	■			IEC 60601-1-6 (usability of medical electrical equipment); ISO 9241 (ergonomics of human-system interaction)		■	■		design for easy reading of status, survey users
M4		distractions	no alarms; no flashing		■		■	■		■		no alarms or flashing lights; simple notification of blow off		■		IEC 62366:2007 (medical device usability); AAMI-HE75 (human factors for medical devices); Kaye, 2000 (FDA)		■			design per standards
M5		physical work	currently physicians and nurses are required to exert themselves significantly to perform a successful reduction; this causes fatigue		■		■	■				should reduce physical exertion when compared with the predicate device	■			interview with nurse and physician indicated excessive physical exertion (Grattan-Smith, 2015; Mahaffey, 2015)			■		user trials on test bed comparing new and predicate device for fatigue
M6		tactile feedback	a way for the physician to make real the pressure via feedback and perhaps interact directly		■		■					should provide adequate tactile feedback, using ISO 9241 (ergonomics of human-system interaction) as guidance			■	ISO 9241 (ergonomics of human-system interaction)		■	■		analysis against standard practices along with user trials
M7		feedback for end states	the physician should easily know if rupture or reduction has occurred	■			■					will notify radiologist if an end state (reduction or perforation) has occurred			■	(Grattan-Smith, 2015; Mahaffey, 2015)	■				compare ability of device to predict end states to actual presence of end states
M8		instructions for use (IFU)	easily understood IFU			■	■	■				conforms to ISO 37 (IFUs), is easy for new users to use		■		ISO 37 (IFUs)		■	■		compatibility with specifications and user trial
N1	Regulatory	biocompatibility	general medical stuff			■			■		■	ensure materials are biocompatible over device lifespan		■		ISO 10993 (biological evaluation of medical Devices), USP VI (implantable materials)	■	■			analysis of known material properties and accelerated aging
N3		unique device identification (UDI) compliance	plan for upcoming UDI guidance implementation			■					■	every device uniquely identified per FDA guidance		■		FDA guidance on UDI		■		■	design in UDI and inspect
O1	Research	data storage capability	ability to plug in a USB drive and extract a csv file with pressure, duration, date and other relevant data	■			■			■	■	ability to plug in a USB drive and extract a csv file with pressure, duration, date and other relevant data			■	IEC 62680 (USB)			■		successfully place patient information less data onto standard USB storage device