

rqmt. #	Importance	Source	Function
S1	9	CN1	System Operation
S2	3	CN2	System Operation
S3	9	CN3	System Operation
S4	9	CN4	System Operation
S5	3	CN5	System Operation
S6	9	CN6	System Operation
S7	9	CN7	System Operation
S8	9	CN8	System Operation
S9	9	CN9	System Operation
S10	9	CN11	System Operation
S11	3	CN12	System Operation
S12	3	CN13	System Operation
S13	1	PRP	
S14	4	CN14, CN15	System Operation
S15	4	CN14, CN15	System Operation
S16	4	CN15	System Operation
S17	4	CN17	System Operation
S18	9	ISO 80601-2-12	System Operation
S19	9	ISO 80601-2-12	System Operation
S20	4	ISO 80601-2-12	System Operation
S24	9	ISO 80601-2-12	System Operation

PEV VALIDATION PROCEDURES

Engr. Requirement (metric)	Specification (Metric)	Unit of Measure	Marginal Value	Ideal Value
Lung Compliance		L/cm H2O		0.1
Resistance of Trachea & Lung		cm H2O/L/sec		0.5-1.5
Rate of air intake	Flow Rate	breaths/min		12-20 for adults
PEEP level	Pressure	psi		0.07
Tidal Volume	Flow Rate	mL		0.0005
Inhale/Exhale Ratio				2 to 1
Air Pressure	Pressure	cm H2O		0-108
Maximum lung volume	Flow Rate	L		6
Flow rate	Flow Rate	L/sec		
Minimum Oxygen Concentration				88 - 100
Maximum Carbon Dioxide Concentration				
Expense of parts		Dollars		1000
Weight	Weight	kg		40
Vibration test		radians/sec		
Drop test		PSI		
Ergonomics of the PEV		multiple units		
EMI test of PEV		kV/m		
Performance of PEV system alarms				
Connection btwn human and PEV		kPa		
Battery life of PEV		hours		
Clear PEV of pathogens				

Comments/Status	Test Plan	Concluded Condition
For an adult.	S1 Test Plan	
For an adult.	S2 Test Plan	
(30-60 at birth)	S3 Test Plan	
	S4 Test Plan	
	S5 Test Plan	
	S6 Test Plan	
	S7 Test Plan	
For an adult.	S8 Test Plan	
	S9 Test Plan	
Due to time constraints, this will not be tested.		
Due to time constraints, this will not be tested.		
Stated in PRP but not stressed by customer.	S13 Test Plan	
Limited PEVs, this will not be tested.		
Limited PEVs, this will not be tested.		
Due to time constraints, this will not be tested.		
Due to time constraints, this will not be tested.		
Push to levels that make alarm sound.	S18 Test Plan	
Outside of project scope.		
Outside of project scope.		

S5

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