A Appendix: Formalised Requirements in FRETISH

Table 1: FRETISH Requirements.

Req ID	FRETISH			
CONT1				
CONT1_1	<pre>in StartUpMode Controller shall eventually satisfy initStart & (initDone (initFail & OutOfServiceWarning & FailSafeMode))</pre>			
CONT1_3	in StandbyMode Controller shall always satisfy ventilationOff & inValveClose & outValveOpen			
CONT1_6	in FailSafeMode Controller shall always satisfy inValveClose & outValveOpen			
CONT2	<pre>if powerOff & !powerButton Controller shall always satisfy !StartUpMode</pre>			
CONT3	in StartUpMode when initDone Controller shall at the next timepoint satisfy SelfTestMode			
CONT4	in SelfTestMode if selfTestPassed GUIResumeRequest Controller shall at the next timepoint satisfy StandbyMode			
CONT5	in StandbyMode if PSVModeSelected Controller shall at the next timepoint satisfy PSVMode			
CONT6	in StandbyMode if PCVModeSelected Controller shall at the next timepoint satisfy PCVMode			
CONT7	in PCVMode if inspiratoryPhaseEnd & PSVModeSelected Controller shall at the next timepoint satisfy ventilating & PSVMode			
CONT8	in PCVMode if stopVentilation Controller shall at the next timepoint satisfy StandbyMode			
CONT9	in PSVMode when breathingTime >= apneaLagTime Controller shall at the next timepoint satisfy PCVMode & RR = RR_AP & P_insp = P_inspAP & ItoE = ItoE_AP			
CONT10	in PSVMode if stopVentilation Controller shall at the next timepoint satisfy StandbyMode			
CONT11	if powerOff Controller shall at the next timepoint satisfy FinalState			
CONT11_1	<pre>in FinalState Controller shall eventually satisfy parametersStored & off</pre>			
CONT12	in StartUpMode Controller shall eventually satisfy defaultParamsLoaded			
CONT13	<pre>in StartUpMode Controller shall eventually satisfy checkCommsSensors & checkCommsValves</pre>			
CONT14	in StartUpMode Controller shall eventually satisfy checkCommsGUI			
CONT15	in StartUpMode if pressureSensorRetries >= 5 & (pressureSensorConnFailure pressureSensorError) Controller shall at the next timepoint satisfy FailSafeMode			
CONT16	in StartUpMode if ADCRetries >= 5 & (ADCConnFailure ADCError) Controller shall at the next timepoint satisfy FailSafeMode			

CONT18	in SelfTestMode Controller shall eventually satisfy selfTestPassed			
	selfTestFailed			
CONT19	in SelfTestMode if SelfTestFail Controller shall until off sat:			
	!StandbyMode & !ventilating			
CONT20	in PCVMode Controller shall always satisfy breathingCycleTime =			
	1/RR_PCV & ExpiratoryTime = breathingCycleTime / (1+ItoE_PCV)			
CONT21	in PCVMode when BreathingCycleStart Controller shall at the next			
	timepoint satisfy inspiratoryPhaseStart			
CONT22	in PCVMode Controller shall always satisfy inspiratoryTime =			
CONT23	60*(ItoE_PCV/(RR_PCV * (1 + ItoE_PCV)))			
CON 125	while PCVMode & inspiratoryPauseButton when inspiratoryPhaseEnd Controller shall for 40 seconds satisfy (inspiratoryPauseButton =>			
	inValveClose & outValveClose)			
CONT24	while PCVMode & RMButton when inspiratoryPhaseEnd Controller shall			
CON124	at the next timepoint satisfy RM			
CONT25	in PCVMode Controller shall always satisfy (breathingCycleDone			
0011120	patientBreathingRequest) => (breathingCycleStart &			
	inspiratoryPhaseStart)			
CONT26	while PCVMode when dropPAW > ITS_PCV Controller shall at the next			
	timepoint satisfy patientBreathingRequest			
CONT27	in PCVMode when expiratoryPauseButton & ExpiratoryPhaseEnd			
	& !patientBreathingRequest Controller shall until			
	buttonUnPressOr6OSeconds satisfy expirationPhaseEnd &			
	inValveClose & outValveClose			
CONT28	in PCVMode Controller shall always satisfy P_insp = P_inspPCV			
CONT30	in PSVMode when BreathingCycleStart Controller shall at the next			
	timepoint satisfy inspiratoryPhaseStart			
CONT32	in PSVMode Controller shall until (P_insp >= MaxP_insp inspClock			
COMESS	>= inspiratoryTime) satisfy inspiratoryPhase			
CONT33	in PSVMode when V_E < ExpiratoryTriggerSensitivity*PeakV_E			
	Controller shall at the next timepoint satisfy			
CONT34	expirationPhaseStart while PSVMode & inspiratoryPauseButton when inspiratoryPhaseEnd			
CON134	Controller shall for 40 seconds satisfy (inspiratoryPauseButton =>			
	inValveClose & outValveClose)			
CONT35	while PSVMode & RMButton when inspiratoryPhaseEnd Controller shall			
0011100	at the next timepoint satisfy RM			
CONT36 1	while PSVMode & expiratoryPhase when dropPAW > ITS_PSV Controller			
_	shall at the next timepoint satisfy patientBreathingRequest			
CONT36 2				
· · · · · · · · · · · · · · · · · · ·	apneaLagTime & !patientBreathingRequest Controller shall			
	until buttonUnPressOr60Seconds satisfy expirationPhaseEnd &			
	inValveClose & outValveClose			
CONT36_3	in PSVMode Controller shall always satisfy minExpiratoryTime			
	>= 0.4 & minExpiratoryTime <= 2 & (expiratoryPhase =>			
	<pre>minExpiratoryTime = inspClock/2)</pre>			

CONT37	in PSVMode when expClock >= apneaLagTime Controller shall at the next timepoint satisfy apnea & PCVMode & RR = RR_AP & P_insp =
	P_inspAP & ItoE = ItoE_AP
CONT38	while StartUpMode StandbyMode Controller shall always satisfy
	inValveClose & outValveOpen
CONT39	while inspiratoryPhase Controller shall always satisfy outValveClose
	& (PCVMode & !apnea => P_insp = P_isnpPCV) & (PSVMode => P_insp
	= P_inspPSV) & (PCVMode & apnea => P_insp = P_inspAP)
CONT40	while expiratoryState Controller shall always satisfy inValveClose & outValveOpen
CONT41	while (PCVMode PSVMode) when inspiratoryPauseButton
0011111	Controller shall eventually satisfy inspiratoryPause
	!inspiratoryPauseButton
CONT41 1	
0011111_1	inspiratoryPhaseEnd Controller shall at the next timepoint satisfy
	(inspiratoryPauseButton => inspiratoryPause & inValveClose &
	outValveClose)
CONT41 2	when inspiratoryPause Controller shall after 40 seconds satisfy
	!inspiratoryPause & expirationPhaseStart
CONT42	while (PCVMode PSVMode) when expiratoryPauseButton Controller
0011112	shall eventually satisfy expiratoryPause !expiratoryPauseButton
CONT42 1	v v i
0011112_1	expiratoryPhaseEnd Controller shall at the next timepoint satisfy
	(expiratoryPauseButton => expiratoryPause & inValveClose &
	outValveClose)
CONT42 2	when expiratoryPause Controller shall after 40 seconds satisfy
	!expiratoryPause & inspiratoryPhaseStart
CONT43	while (PCVMode PSVMode) & RMButton & !inspiratoryPauseButton
	when inspiratoryPhaseEnd Controller shall at the next timepoint
	satisfy RM
CONT43 1	while RM if !RMButton Controller shall at the next timepoint satisfy
_	!RM & expirationPhaseStart
CONT43 2	when RM Controller shall after 10 seconds satisfy !RM &
_	expirationPhaseStart
CONT43 3	while RM Controller shall always satisfy outValveClose & inValveOpen
CONT44	if P_insp > MaxP_insp Controller shall at the next timepoint
	satisfy inspiratoryPhaseEnd & expirationPhaseStart
CONT45	when expirationPhaseStart Controller shall after 700 milliseconds
	satisfy monitorInhaleTrigger
CONT46	after FailSafeMode Controller shall until off satisfy !(StartUpMode
	SelfTestMode StandbyMode PCVMode PSVMode)
FUN4	System shall always satisfy StartUpMode SelfTestMode
1 0111	StandbyMode PCVMode PSVMode FailSafeMode
FUN5	when powerButton & (breathingCircuitConnected &
~ - · · ·	!(patientConnected) & airSupplyConnected & powerConnected)
	System shall at the next timepoint satisfy StartUpMode
FUN5 1	in StartUpMode System shall eventually satisfy initStart &
~ - · ~ <u>-</u> *	checkCommsSensors & checkCommsValves & checkCommsGUI

FUN5_2	in StartUpMode System shall eventually satisfy initDone (initFail
	& OutOfServiceWarning & FailSafeMode)
FUN5_3	System shall always satisfy (StartUpMode SelfTestMode) ->
	!patientConnected
FUN6	in SelfTestMode System shall eventually satisfy selfTestPassed
	selfTestFailed
FUN6_1	in SelfTestMode System shall eventually satisfy testPowerSwitchPass
	testPowerSwitchFail testPowerSwitchSkip
FUN6_2	in SelfTestMode System shall eventually satisfy testLeaksPass
	testLeaksFail testLeaksSkip
FUN6_3	in SelfTestMode System shall eventually satisfy testF12Pass
	testFl2Fail testFl2Skip
FUN6_4	in SelfTestMode System shall eventually satisfy testPSExpPass
	testPSExpFail testPSExpSkip
FUN6_5	in SelfTestMode System shall eventually satisfy testOxygenSensorPass
_	testOxygenSensorFail testOxygenSensorSkip
FUN6 6	in SelfTestMode System shall eventually satisfy testAlarmsPass
_	testAlarmsFail testAlarmsSkip
FUN7	in SelfTestMode if selfTestFail System shall at the next timepoint
	satisfy OutOfServiceWarning & FailSafeMode
FUN8	System shall always satisfy logParams & saveLog & loadLog
FUN8 5	System shall always satisfy if user = operator then !eraseLog
FUN8 6	when ventilatorSettingsChanged System shall at the next timepoint
_	satisfy logVentilatorSettings
FUN8 7	when alarmSettingsChanged System shall at the next timepoint
_	satisfy logAlarmSettings
FUN8 8	when patientChanged System shall at the next timepoint satisfy
_	logPatientChange
FUN8 9	when powerSupplyChanged System shall at the next timepoint satisfy
_	logPowerSupply
FUN8 10	when preUseCheckDone System shall at the next timepoint satisfy
_	logPreUseCheck
FUN8 11	System shall always satisfy logO2SensorUse
FUN8 12	System shall always satisfy logVentilationParams & logAlarmParams
_	& logCalibrationParams
FUN9	when selfTestPassed System shall at the next timepoint satisfy
	startMonitoring & startReportingHealthParams & StandbyMode
FUN10	when startUpDone System shall eventually satisfy newPatient
-	resumeVentilation
FUN10 1	when newPatient System shall eventually satisfy
	patientAttributesEntered & SelfTestMode & ((testPowerSwitchPass
	& testLeaksPass & testFl2Pass & testPSExpPass &
	testOxygenSensorPass & testAlarmsPass) => selfTestPassed)
FUN10 2	when resumeVentilation System shall at the next timepoint satisfy
· · · · ·	loadLastParams

FUN10_3	when resumeVentilation System shall eventually satisfy			
	SelfTestMode & (((testPowerSwitchPass testPowerSwitchSkip) &			
	<pre>(testLeaksPass testLeaksSkip) & (testF12Pass testF12Skip)</pre>			
	& (testPSExpPass testPSExpSkip) & (testOxygenSensorPass			
	testOxygenSensorSkip) & (testAlarmsPass testAlarmsSkip)) =>			
	selfTestPassed)			
FUN10 4	when selfTestPassed System shall at the next timepoint satisfy			
	StandbyMode			
FUN10 5	in StandbyMode System shall always satisfy ventilationOff &			
_	ventilationParmsAdjustable			
FUN10 6	when off System shall after 15 minutes satisfy !resumeVentilation			
FUN11	System shall always satisfy GBPS <= 5.2			
FUN13	System shall always satisfy measureRR & displayRR			
FUN14	System shall always satisfy measure02% & display02%			
FUN15	System shall always satisfy measurePSins			
FUN16	System shall always satisfy measureTV & displayTV			
FUN17	System shall always satisfy measureFl1 & display Fl1			
FUN18	System shall always satisfy (if enableLeakCompensation then			
_ 01.10	leakCompensation !leakCompensation			
FUN18 1	System shall always satisfy (if enableLeakCompensation			
1 01110_1	then leakCompensation) & (if disableLeakCompensation then			
	(!leakCompensation & !enableLeakCompensation))			
FUN18 2	when leakCompensationEnable if MinPEEPAlarm System shall at the			
1 01110_2	next timepoint satisfy leakCompensationActive			
FUN20	in PCVMode System shall always satisfy breathingCycleTime = 1/RR_PCV			
1 011.20	& ExpiratoryTime = breathingCycleTime / (1+ItoE_PCV)			
FUN21	in PCVMode System shall always satisfy (breathingCycleDone			
2 011.21	patientBreathingRequest) => breathingCycleStart			
FUN21 1	when inspiratoryPressure < InhaleTriggerSensitivityPCV System			
	shall at the next timepoint satisfy breathingCycleStart			
FUN21 2	when patientBreathTrigger System shall at the next timepoint			
	satisfy breathingTimerReset			
FUN22	in PCVMode when RMButton System shall at the next timepoint satisfy			
_ 01.22	RM			
FUN23	in PCVMode when PSVModeSelected System shall at the next timepoint			
1 01120	satisfy ventilating & PSVMode			
FUN23 1	in PCVMode when PSVModeSelected System shall eventually satisfy			
1 01120_1	confirmPSVParameters			
FUN23 2	in PCVMode System shall always satisfy ((confirmPSVParameters &			
1 01120_2	PSVMode) (!confirmPSVParameters & PCVMode)) & ventilating			
FUN23 3	in PCVMode when PSVModeSelected System shall at the next timepoint			
1.01/29_9				
FIINOE	satisfy !(PCVInspTimeEnd & PSVMode) in PSVMode when inspiratoryPressure <			
FUN25				
	InhaleTriggerSensitivityPSV System shall at the next timepoint			
FUN26	satisfy breathingCycleStart			
r unzo	in PSVMode when Fl1 < ExpiratoryTriggerSensitivity System shall at			
	the next timepoint satisfy expirationPhaseStart			

FUN27	in PSVMode when breathingTime >= apneaLagTime System shall at the
	next timepoint satisfy apnea
FUN27 1	if apnea System shall at the next timepoint satisfy apneaAlarm
FUN27 2	if apnea System shall at the next timepoint satisfy PCVMode & RR =
_	RR_AP & P_insp = P_inspAP & ItoE = ItoE_AP
FUN28	when expiratoryPauseButton & (ExpiratoryPhaseEnd) System shall
	until buttonUnPressOr6OSeconds satisfy expirationPhaseEnd &
	inValveClose & outValveClose
FUN29	while inspiratoryPauseButton when (inspiratoryPhaseEnd)
	System shall for 40 seconds satisfy (inspiratoryPauseButton =>
	inValveClose & outValveClose)
FUN30	System shall always satisfy if StartUpMode then (if newPatient
	then SelfTestMode & if !newPatient then StandbyMode) & if
	SelfTestMode then (if selfTestPassed then StandbyMode) & if
	StandbyMode then (if startPCV then PCVMode & if startPSV then
	PSVMode & if runSelfTest then SelfTestMode) & if error then
FUN31	FailSafeMode & if powerOff then off
FUN31 FUN32	System shall always satisfy patientSafe
FUN33	in FailSafeMode System shall always satisfy patientSafe
r UN33	if powerFailure System shall at the next timepoint satisfy patientSafe
FUN34	if gasSupplyFailure System shall at the next timepoint satisfy
1 01134	patientSafe
FUN37	if powerFailure System shall for 120 minutes satisfy !off
FUN38_1	if param_V > paramMax_V param_V < paramMin_V System shall at the
	next timepoint satisfy paramAlarm_V
FUN39	before PSVMode PCVMode System shall eventually satisfy
	enterAlarmThresholds
FUN40	if P_insp > MaxP_insp System shall at the next timepoint satisfy
	<pre>inspiratoryPhaseEnd & expirationPhaseStart</pre>
FUN41	if GUIFailue !GUIConnected System shall at the next timepoint
	satisfy ventilating & highPriorityAlarm