URS

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Published on: 21-Oct-2021

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Chapter 1: Requirement Set: URS

Description

This is the specifications that have been stated within the URS for th ventilator and will be assigned to the model.

Implementation Status

Total: 197, Implemented: 6, Justified: 0, None: 191

Verification Status

Total: 197, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 1, None: 196

Change Information [Change issue(s) found in 5 requirement(s).](#ChangedLinkListTable)

1 Power Supply to all Sub-systems

Requirement Type Functional

ID SysOP-61

Description

The power supply sub-system shall be capable of providing electrical power to all the sub-systems of the BVS

Keywords

Power Supply

Change Information No change issue detected.

Links

Artifact: [BiPAP\_Architecture.slx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| BiPAP\_Architecture:35 | Implemented by |

Artifact: [URS.slreqx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| URS.slreqx:3 | Verified by |

Implementation Status

Total: 13, Implemented: 1, Justified: 0, None: 12

Verification Status

Total: 13, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 1, None: 12

1.1 Main on/off

Requirement Type Functional

ID SysOP-61-C1

Description

The system shall allow for the main on/off switch to activate standby mode, secondary function to turn the device on from standby mode.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.2 Run Time

Requirement Type Functional

ID SysOP-61-C2

Description

The system shall be able to run for a minimum of 14 days without failure and/or maintenance.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.3 Mains Power

Requirement Type Functional

ID SysOP-61-C3

Description

The system shall work from standard (South Africa 2021) 220 Volt (V) Alternating Current (AC) 50 Hertz (Hz) wall socket.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.4 Cable length

Requirement Type Functional

ID SysOP-61-C4

Description

The system shall be provided with a mains cable that is three meters long.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.5 Mains Connector

Requirement Type Functional

ID SysOP-61-C5

Description

The mains cable shall be fitted with SANS 164-4:2018 complient 15A three prong plug.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.6 Cable Prongs

Requirement Type Functional

ID SysOP-61-C6

Description

The earth pin shall be fitted to the top with a red cover.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.7 Power Failure

Requirement Type Functional

ID SysOP-61-C7

Description

In the case of power failure the system shall be able to switch from AC main power to battery operated mode.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.8 Power Resume

Requirement Type Functional

ID SysOP-61-C8

Description

The system shall switch from battery operating power to AC mains power when power is reconnected to the system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.9 Battery Run Time

Requirement Type Functional

ID SysOP-61-C9

Description

The system shall be able to provide uninteruprted power supply from battery backup for a time period of atleast an hour when main power supply fails (NVPF3.16.1).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.10 Electrical Safety

Requirement Type Functional

ID SysOP-61-C10

Description

The systems shall be complient with Electromagnetic Complience EMC and Elevtromagnetic Interference EMI requirements as set by IEX60601, Electrical Safety1-1.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.11 Subsection Supply

Requirement Type Functional

ID SysOP-61-C11

Description

The system shall be able to privide power to the system through the control subsystem without power drop out or failure.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

1.12 Power Cable Clamp

Requirement Type Functional

ID SysOP-61-C12

Description

The system shall have a cable that keep the power cable connected to the system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2 Control Subsystem Primary Monitor

Requirement Type Functional

ID SyOPS-62

Description

The Control Sub-system shall be capable of performing all the primary monitoring and control functions of the BVS.

Keywords

HMI Control

Change Information [Change issue detected.](#ChangedLinkListTable)

Links

Artifact: [BiPAP\_Architecture.slx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| BiPAP\_Architecture:35 | Implemented by |
| BiPAP\_Architecture:16 | Implemented by |

Implementation Status

Total: 58, Implemented: 1, Justified: 0, None: 57

Verification Status

Total: 58, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 58

2.1 Presssuer over time

Requirement Type Functional

ID SyOPS-62-C1

Description

Pressure ramp option that starts pressure at low level (minimum) and increases slowly over time priod to set level (User set maximum).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.2 Spontanious Timing

Requirement Type Functional

ID SyOPS-62-C2

Description

The BVS shall react to spontanious timing in reaction to the breathing of the patient.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.3 Rebreathing

Requirement Type Functional

ID SyOPS-62-C3

Description

The system shall account for 4 to 5 millimeters of CO2 rebreathing.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.4 APAP

Requirement Type Functional

ID SyOPS-62-C4

Description

The system shall allow for automatic positive airway pressure also called AutoPAP or APAP

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.5 CPAP

Requirement Type Functional

ID SyOPS-62-C5

Description

The system shall be CPAP spontanious for a time (T) Pressure Assisted Control/Pressure COntrole (PAC/PC)

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.6 Inspirator and Exiratory

Requirement Type Functional

ID SyOPS-62-C6

Description

The system shall allow for the programmable time functions for inspiratory and expiratory

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.7 Rise Time to Peak Flow

Requirement Type Functional

ID SyOPS-62-C7

Description

The system shall be controlled ro prevent massive increase in airflow, variable rate shall be selectable.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.8 Inspiration to Expiration

Requirement Type Functional

ID SyOPS-62-C8

Description

The system shall allow the fan to operate at 30% to 50% of the peak flow rate.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.9 Exspiration to Insiration

Requirement Type Functional

ID SyOPS-62-C9

Description

The system shall allow for the flow to chang eercentage when inspiration is trggered to peak flow cycle.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.10 Operation

Requirement Type Functional

ID SyOPS-62-C10

Description

The system shall operate without fail for a minimum period of 14 days.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.11 Low Level Alarm

Requirement Type Functional

ID SyOPS-62-C11

Description

The system shall trigger an low level alarm when a low catagory failure occures while device continues function on last preset with limited capabilities.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.12 High Levle Alarm

Requirement Type Functional

ID SyOPS-62-C12

Description

The system shall trigger a high level alarm when critical failure in a main component failure, built in safty systems shall open the patient circuit to prevent obstruction.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.13 Start-Up

Requirement Type Functional

ID SyOPS-62-C13

Description

The system shall send start up function to the HMI when system is power up.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.14 Self Test

Requirement Type Functional

ID SyOPS-62-C14

Description

The system shall be capable of iniciting self testing procedure when triggered by HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.15 Information Set

Requirement Type Functional

ID SyOPS-62-C15

Description

The system shall allow for the medical practitioner to set the operations

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.16 Initiate Therapy

Requirement Type Functional

ID SyOPS-62-C16

Description

The system shall when triggeed by the medical practitioner inicicate the preset therapy to the patient iniciating ventilation from the Air Supply Subsystem.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.17 Auditory Check

Requirement Type Functional

ID SyOPS-62-C17

Description

The system shall detect auditory feedback via a mic or LDR.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.18 Maintinance Mode Trigger

Requirement Type Functional

ID SyOPS-62-C18

Description

The system shall be capable of entering maintainance when both button and password have been triggered.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.19 Monitoring

Requirement Type Functional

ID SyOPS-62-C19

Description

The system shall provide the HMI with monitoring infomation of the patient and system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.20 Shut Down Mode

Requirement Type Functional

ID SyOPS-62-C20

Description

the system shall allow the operator to shutdown the unit from the HMI provided the system has not locked out shutdown either physcally or in software.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.21 Lock out

Requirement Type Functional

ID SyOPS-62-C21

Description

The system shall allow the operator to physically or in software allow for locking shutdown sequence

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.22 Shutdown Routine

Requirement Type Functional

ID SyOPS-62-C22

Description

The system shall enter standby mode and apon wake up or turning on the system shal go inti Start-up mode.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.23 Self Fuction from Software

Requirement Type Functional

ID SyOPS-62-C23

Description

The system shall allow for self testing procedure when triggered by HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.24 Maintainance Self Test

Requirement Type Functional

ID SyOPS-62-C24

Description

The system shall allow for self testing procedure during maintainance mode

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.25 Low Pressure Alarm

Requirement Type Functional

ID SyOPS-62-C25

Description

The system shall allo for the setting of the low pressure alarm through the HMI by the operator or support equipment.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.26 Scalable Pressure Alarm

Requirement Type Functional

ID SyOPS-62-C26

Description

The system shall allow for the alarm state to be monitored and escilated if the alarm has not clear within a time period.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.27 Alarm Trigger System Failure

Requirement Type Functional

ID SyOPS-62-C27

Description

The system shall trigger high level alarm when system failure is detected.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.28 Alarm Trigger Power Failure

Requirement Type Functional

ID SyOPS-62-C28

Description

The system shall trigger low level alarm when mains power is unavaiable.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.29 Alarm Trigger Battery Back Up Failure

Requirement Type Functional

ID SyOPS-62-C29

Description

The system shall allow for High Level alarm trigger when battery backup is low on power and main power is unavailable.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.30 Technical Alarm

Requirement Type Functional

ID SyOPS-62-C30

Description

The system shall be abke to trigger a technical alarm.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.31 Equipment Alarm

Requirement Type Functional

ID SyOPS-62-C31

Description

The system shall allow for high level alarm for leak detection.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.32 Service Alarm

Requirement Type Functional

ID SyOPS-62-C32

Description

System shall trigger technical alram and show service needed on HMI 1 month before service date

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.33 Air Filter Alarm

Requirement Type Functional

ID SyOPS-62-C33

Description

The system shall trigger air filter replacement technical alram and display on HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.34 Alarm Set

Requirement Type Functional

ID SyOPS-62-C34

Description

The alarms shall be set to system defult within tqo minutes of startup

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.35 Silence Alarm

Requirement Type Functional

ID SyOPS-62-C35

Description

The system shall allow to alarms to be silenced for a maximum of two minutes.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.36 Patient Alarm Cancle

Requirement Type Functional

ID SyOPS-62-C36

Description

The system shall allow for the alarm to be cleared once the patient has take three full breaths.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.37 Self Test Method

Requirement Type Functional

ID SyOPS-62-C37

Description

The system shall condcut the self test automatically during startup or when actioned by the user through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.38 Instructions

Requirement Type Functional

ID SyOPS-62-C38

Description

The system shall provide the procedures to do self test in the manual.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.39 Healthcare Instructions

Requirement Type Functional

ID SyOPS-62-C39

Description

The system shall provide a test method for the healthcare operator.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.40 Internal Timer

Requirement Type Functional

ID SyOPS-62-C40

Description

The system shall have an internal timer for various actons to take place.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.41 Operator Control IPAP

Requirement Type Functional

ID SyOPS-62-C41

Description

The system shall allow the operator to control the Inhalation Pressure (IPAP) from the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.42 Exhalation Pressure EPAP

Requirement Type Functional

ID SyOPS-62-C42

Description

The system shall allow the operator to control the Exhalation Pressure (EPAP) through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.43 Apnoea Period

Requirement Type Functional

ID SyOPS-62-C43

Description

The system shall allow the operator to control the Apnoea Period through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.44 Inspired Oxygen Proportion (FiO2)

Requirement Type Functional

ID SyOPS-62-C44

Description

The system shall allow the operator to control the Inspired Oxygen Proportion (FiO2) through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.45 Inspirtory Trigger Pressure

Requirement Type Functional

ID SyOPS-62-C45

Description

The system shall allow the operator to control the Inspritory trigger based on pressure through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.46 Time to Peak flow

Requirement Type Functional

ID SyOPS-62-C46

Description

The system shall allow the operator to control the Time th Peak Flow through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.47 Inspiratory Trigger Range

Requirement Type Functional

ID SyOPS-62-C47

Description

The system shall allow for the inpritory trigger range from -0.5 to -15 cmH2O

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.48 Two Pressure Settings

Requirement Type Functional

ID SyOPS-62-C48

Description

The system shall allow for two pressure settings being Inhalation (IPAP) and Exhalation (EPAP).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.49 Spontanious Inhalation Patient Iniciated

Requirement Type Functional

ID SyOPS-62-C49

Description

The system shall allow the operator to set the apnoea threshhold through the HMI for the alarm trigger.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.50 Inspiration Oxygen Proportion (FiO2)

Requirement Type Functional

ID SyOPS-62-C50

Description

The system shall allow the operator through the HMI to set the inspired oxygen proportion (FiO2) of the gass supplied to the patient from 21% to 100% in set incements of 10% or with a contious slider with an accuracy of 5%.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.51 Flow Rate

Requirement Type Functional

ID SyOPS-62-C51

Description

The system shall allow the operator through the HMI to set the average flow rate from 10 to 80 L/min with limit of PEEP of 4 to 20 cmH2O

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.52 Pressure Range IPAP

Requirement Type Functional

ID SyOPS-62-C52

Description

The system shall allow the pressure of the IPAP to be set from 4 to 25 cmH2O

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.53 Pressure Range EPAP (PEEP)

Requirement Type Functional

ID SyOPS-62-C53

Description

The system shall allow for the EPAP (PEEP) to be set on the range of 4-20 cmH2O

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.54 Pressure Range CPAP

Requirement Type Functional

ID SyOPS-52-C54

Description

The system shall allow for the range to be set within 4-15 cmH2O

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.55 Data Logging Monitoring

Requirement Type Functional

ID SyOPS-52-C55

Description

The system shall data log all monitored Items from the HMI keeping the information saved

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.56 Data Download

Requirement Type Functional

ID SyOPS-52-C56

Description

The system shall allow for the data captured in the monitring system to be downloaded for analysis.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

2.57 Technical Alarm High Priority

Requirement Type Functional

ID SyOPS-52-C57

Description

The system shall allow for the high priority technical alarm to be cleared by medical personal but is to be recored then alwarm is sileced and acknowladged.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3 HMI Primary control and interface

Requirement Type Functional

ID SyOPS-63

Description

The HMI Sub-system shall be the primary display and control interface between the medical operator and the BVS.

Change Information [Change issue detected.](#ChangedLinkListTable)

Links

Artifact: [BiPAP\_Architecture.slx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| BiPAP\_Architecture:32 | Implemented by |

Implementation Status

Total: 57, Implemented: 1, Justified: 0, None: 56

Verification Status

Total: 57, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 57

3.1 Trigger Sensativity cmH2O

Requirement Type Functional

ID SyOPS-63-C1

Description

The system shall allow for the HMI to have a trigger sensativaty of 1-10 cmH2O in incroments of 1 cmH2O or be automatic.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.2 Start-up Screen

Requirement Type Functional

ID SyOPS-63-C2

Description

The system shall have a start up screen sequence when powered on.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.3 Start-up Prompt Self Test

Requirement Type Functional

ID SyOPS-63-C3

Description

The system shall allow the user to start the mantidory self test process on the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.4 Start-up Predefine Setting Screen

Requirement Type Functional

ID SyOPS-63-C4

Description

The system shall show a screen of predefined peramiters for the ventilator that may be edited for each setting that is elable for change by the health practitioner.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.5 Start-up Balance System

Requirement Type Functional

ID SyOPS-63-C5

Description

The system shall allow for chnges to be saved in the startup process where all changes will be shown and confirmed.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.6 Start-up Black Box

Requirement Type Functional

ID SyOPS-63-C6

Description

The system shall record all the changes that were within safe messure and monitor errors on the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.7 Start-up Iniciate Therapy

Requirement Type Functional

ID SyOPS-63-C7

Description

The system shall allow for the confirmation of iniciation of ventilating therapy for patient.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.8 Maintenance Mode Notification and Password

Requirement Type Functional

ID SyOPS-63-C8

Description

The system shall inform the operator on the HMI that the system has entered maintenance mode and qill promt for a code to enter maintenance.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.9 Practicioners Settings

Requirement Type Functional

ID SyOPS-63-C9

Description

While ventilating the setting f=of the practioner shall be locked with a key that the practioner has set.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.10 Calibration Test

Requirement Type Functional

ID SyOPS-63-C10

Description

The system shall be capable of running a calibration test (through the self test) through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.11 Monitoring with HMI

Requirement Type Functional

ID SyOPS-63-C11

Description

The system shall allow for system monitoring through the HMI/user interface.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.12 Monitered Parameters

Requirement Type Functional

ID SyOPS-63-C12

Description

The system shall allow for selected parameters to be monitored on the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.13 Touch Screen

Requirement Type Functional

ID SyOPS-63-C13

Description

The system shall utilise a touch screen interface for the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.14 Screen Clean

Requirement Type Functional

ID SyOPS-63-C14

Description

The system shall have a touch screen that can be ceaned and disinfected without damage.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.15 Screen Size

Requirement Type Functional

ID SyOPS-63-C15

Description

The system shall utilise a screen that is 7" or 10" in diameter.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.16 Pernament Monitors

Requirement Type Functional

ID SyOPS-63-C16

Description

The system shall have the following peramitors pernamently shown on the monitor, pressure, flow and volume in a graphic scaler.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.17 Screen Brightness

Requirement Type Functional

ID SyOPS-63-C17

Description

The system shall have a brightnerss that is ledgable in direct sunlight.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.18 Daylight mode

Requirement Type Functional

ID SyOPS-63-C18

Description

The system shall allow for the chnage to nondaylight and daylight mode.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.19 Lung Graphics

Requirement Type Functional

ID SyOPS-63-C19

Description

The system shall have graphics of the lungs during ventilation.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.20 Setting Profile

Requirement Type Functional

ID SyOPS-63-C20

Description

The system shall allow for resumption onthe previous user set settings that is saved to the profile.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.21 Failure HMI Prompt

Requirement Type Functional

ID SyOPS-63-C21

Description

The system shall allow the HMI to visually shaow a failure and the type with information on the failure to appear, the HMI will also allow for the silencing prompt of the alarm (while inline of the settings of the system for the level of alarm)

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.22 Secondary Input

Requirement Type Functional

ID SyOPS-63-C22

Description

The system shall allow for a secondary input through a control knob.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.23 Control IPAP

Requirement Type Functional

ID SyOPS-63-C23

Description

The system shall allow for the operator to set the perameters in the HMI of Inhalation Pressure (IPAP) while being able to control the settings.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.24 Apnoea Period HMI

Requirement Type Functional

ID SyOPS-63-C24

Description

The system shall allow for the operator to set and manage the apnoea time period.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.25 Inspired Oxygen HMI

Requirement Type Functional

ID SyOPS-63-C25

Description

The system shall allow the user to set the inspired oxygen proprtion (FiO2).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.26 Exhalation Pressure (EPAP)

Requirement Type Functional

ID SyOPS-63-C26

Description

The system shall allow for the operator to set the exhalation Pressure (EPAP).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.27 Inspiratory Trigger Pressure Set

Requirement Type Functional

ID SyOPS-63-C27

Description

The system shall allow for the operator to set the Inspiration trigger point through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.28 Peak Flow Time Set

Requirement Type Functional

ID SyOPS-63-C28

Description

The system shall allow the operatore to set the time to peak flow through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.29 Insparatory Trigger Range

Requirement Type Functional

ID SyOPS-63-C29

Description

The system shall allow the operatore to set the inspiratory trigger from -0.5 to -15 cmH2O through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.30 Pressure setting

Requirement Type Functional

ID SyOPS-63-C30

Description

The system shall allow the operatore to set the IPAP and EPAP seperately through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.31 Apnoea Alarm Set

Requirement Type Functional

ID SyOPS-63-C31

Description

The system shall allow the operatore to set the apnoea alarm limit from 10 to 40 seconds through the HMI. (NVP F.1.4)

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.32 FiO2 Percentage Set

Requirement Type Functional

ID SyOPS-63-C32

Description

The system shall allow the operatore to set the inspired oxygen proportion (FiO2) from 21% to 100% with accuracy of 5% through the HMI. (NVP F.7.1)

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.33 IPAP Setting Range

Requirement Type Functional

ID SyOPS-63-C33

Description

The system shall allow the operatore to set the IPAP from 4-25 cmH2O through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.34 EPAP Setting Range

Requirement Type Functional

ID SyOPS-63-C34

Description

The system shall allow the operatore to set the EPAP from 4 to 20 cmH2O through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.35 CPAP Setting Range

Requirement Type Functional

ID SyOPS-63-C35

Description

The system shall allow the operatore to set the CPAP from 4 to 15 cmH2O through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.36 Monitor IPAP and EPAP

Requirement Type Functional

ID SyOPS-63-C36

Description

The system shall allow for the monitoring of IPAP and EPAP through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.37 Monitoring FiO2

Requirement Type Functional

ID SyOPS-63-C37

Description

The system shall allow for the monitoring of FiO2 through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.38 Monitoring MAP

Requirement Type Functional

ID SyOPS-63-C38

Description

The system shall allow for the monitoring of Mean Airway Pressure (MAP) through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.39 Monitor Time to Peak Pressure

Requirement Type Functional

ID SyOPS-63-C39

Description

The system shall allow for the monitoring of Time to Peak Pressure through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.40 Monitor Inspiration and Expiration Ratio

Requirement Type Functional

ID SyOPS-63-C40

Description

The system shall allow for the monitoring of Inspiration and Exparation Ratio through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.41 Monitor All Variables

Requirement Type Functional

ID SyOPS-63-C41

Description

The system shall allow for the monitoring of all variable that have been set through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.42 Monitor PEEP Pressure

Requirement Type Functional

ID SyOPS-63-C42

Description

The system shall allow for the monitoring of PEEP Pressure through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.43 Monitoring Expiratory Flow Time and Pressure Time

Requirement Type Functional

ID SyOPS-63-C43

Description

The system shall allow for the monitoring of Expiratory Flow and Pressure Time through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.44 Monitor Expired Breath Volume

Requirement Type Functional

ID SyOPS-63-C44

Description

The system shall allow for the monitoring of Expird Breath Volume through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.45 Display Mode Preference

Requirement Type Functional

ID SyOPS-63-C45

Description

The system shall allow the operator to choose the prefered display mode of the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.46 Alarm Pop-ups

Requirement Type Functional

ID SyOPS-63-C46

Description

The system shall display alarm pop-ups when an alarm has been triggered by the control system on the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.47 Test Manuals

Requirement Type Functional

ID SyOPS-63-C47

Description

The system shall allow access to the test manuals through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.48 Test Accessories

Requirement Type Functional

ID SyOPS-63-C48

Description

The system shall allow the operator to test the tubing and accessories from the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.49 Test Power

Requirement Type Functional

ID SyOPS-63-C49

Description

The system shall allow for the operator to switch from main power to battery to test switching capabilaties within the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.50 Alarm Test

Requirement Type Functional

ID SyOPS-63-C50

Description

The system shall allow for all alarm signals and operations to be tested through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.51 Circuit Test

Requirement Type Functional

ID SyOPS-63-C51

Description

The system shall allow the operator to test the circuit disconnect alarm within the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.52 Button Test

Requirement Type Functional

ID SyOPS-63-C52

Description

The system shall allow for the operator to test button verification through the HMI

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.53 Alarm Visual and Audiable Test

Requirement Type Functional

ID SyOPS-63-C53

Description

The system shall allow the operator to test all alarm visuals and alarm tones through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.54 Service Reminder and Check

Requirement Type Functional

ID SyOPS-63-C54

Description

The system shall allow the operator to check when a service is due and get a reminder on month before for service through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.55 QR Code Manual LInk

Requirement Type Functional

ID SyOPS-63-C55

Description

The system shall allow for the operator tp access the user manual via the QR Code trough the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

3.56 Blower Life Time Indicator

Requirement Type Functional

ID SyOPS-63-C56

Description

The system shall allow the operator to see the life time inidcator of the blower through the HMI.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4 Alarm Subsystem alarm activation

Requirement Type Functional

ID SyOPS-65

Description

The Alarm Sub-system shall be capable of actuation of all the alarms of the BVS.

Change Information [Change issue detected.](#ChangedLinkListTable)

Links

Artifact: [BiPAP\_Architecture.slx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| BiPAP\_Architecture:13 | Implemented by |

Implementation Status

Total: 25, Implemented: 1, Justified: 0, None: 24

Verification Status

Total: 25, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 25

4.1 Alarm Peak Pressure

Requirement Type Functional

ID SyOPS-65-C1

Description

The alarm will trigger when a pressure of 40 cmH2O

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.2 Low Catagory Failure

Requirement Type Functional

ID SyOPS-65-C2

Description

The system shall trigger a low level alarm when triggered by the control system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.3 Alarm Critical Failure

Requirement Type Functional

ID SyOPS-65-C3

Description

The system shall allow for critical alarm to be triggered by the control system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.4 Visual and Audio

Requirement Type Functional

ID SyOPS-65-C4

Description

The system shall trigger both audiable and visual ques

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.5 Low Level Visual Alarm

Requirement Type Functional

ID SyOPS-65-C5

Description

The system shall visually indicate low level alarm with an orange LED.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.6 High Level Visual Alarm

Requirement Type Functional

ID SyOPS-65-C6

Description

The system shall visually indicate high level alarm with a red LED.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.7 Technical Visual Alarm

Requirement Type Functional

ID SyOPS-65-C7

Description

The system shall visually indicate a technical alarm with a blue LED.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.8 Alarm Access

Requirement Type Functional

ID SyOPS-65-C8

Description

The system shall allow for the operator to access the perameters of the alarm.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.9 Alarm Volume

Requirement Type Functional

ID SyOPS-65-C9

Description

The system shall be locked so it can not be altered by operators

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.10 Perameters Locked

Requirement Type Functional

ID SyOPS-65-C10

Description

The system shall lock all peramiters of the alarm other than trigger points.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.11 Alarm Descibel Scale

Requirement Type Functional

ID SyOPS-65-C11

Description

The system shall be capable of scalable in decible level or tone when not addressed for two minutes.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.12 Number of Alarms

Requirement Type Functional

ID SyOPS-65-C12

Description

The system shall be limited to three catagories of alarms (technical low level and high level)

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.13 Alarm Limits Violated

Requirement Type Functional

ID SyOPS-65-C13

Description

The system shall trigger the alarm if the limits have been violated

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.14 Breathing Alarm

Requirement Type Functional

ID SyOPS-65-C14

Description

The system shall trigger a high level alarm when the patient shows no breathing effort (NVP F.13.1).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.15 High Low Pressure

Requirement Type Functional

ID SyOPS-65-C15

Description

The system shall trigger the high level alarm if the pressure of the system is outside of the preset high or low range.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.16 Breathing Circuit

Requirement Type Functional

ID SyOPS-65-C16

Description

The system shall trigger a high level alarm when the patient breathing circuit is abruptly disconnected.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.17 Oxygen Supply Failure

Requirement Type Functional

ID SyOPS-65-C17

Description

The system shall trigger a high level alarm when an oxygen supply failure is detected.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.18 Air Supply Failure

Requirement Type Functional

ID SyOPS-65-C18

Description

The system shall trigger a high level alarm when the air supply has failed.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.19 Apnoea Alarm

Requirement Type Functional

ID SyOPS-65-C19

Description

The system shall trigger a high level alarm when apnoea is detected by the control system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.20 High Insieration Rate

Requirement Type Functional

ID SyOPS-65-C20

Description

The system shall trigger a low level alarm when high breathing rate is measured.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.21 High Level Alarm Clear

Requirement Type Functional

ID SyOPS-65-C21

Description

The system shall only allow for high level alarms to be clear only when issue has been resolved.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.22 Technical Type of Alarm

Requirement Type Functional

ID SyOPS-65-C22

Description

The system shall trigger a techniical alarm when battery is running low or service is needed.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.23 Low Level Alarm Type

Requirement Type Functional

ID SyOPS-65-C23

Description

The system shall trigger a low level trigger when minor peramiters set by the operator are violated.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

4.24 High Level Alarm Type

Requirement Type Functional

ID SyOPS-65-C24

Description

The system shall trigger the high level alarm when a system debiliting error ocures.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

5 RMT Subsystem Provide information

Requirement Type Functional

ID SyOPS-66

Description

The Remote monitoring Sub-system shall be capable of providing BVS information to a remote terminal.

Change Information No change issue detected.

Implementation Status

Total: 3, Implemented: 0, Justified: 0, None: 3

Verification Status

Total: 3, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 3

5.1 Remote Monitor

Requirement Type Functional

ID SyOPS-66-C1

Description

The system shall allow for the system to monitored in a location that is convinient for the operator.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

5.2 Mirror

Requirement Type Functional

ID SyOPS-66-C2

Description

The system shall mirror the monitoring screen of the screen on the ventilator.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6 Air Supply Subsystem Air mix

Requirement Type Functional

ID SyOPS-67

Description

The Air Supply Sub-system shall be capable of selecting mixing and regulating the ventilator air stream.

Change Information [Change issue detected.](#ChangedLinkListTable)

Links

Artifact: [BiPAP\_Architecture.slx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| BiPAP\_Architecture:2 | Implemented by |

Implementation Status

Total: 15, Implemented: 1, Justified: 0, None: 14

Verification Status

Total: 15, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 15

6.1 Constant Air Supply

Requirement Type Functional

ID SyOPS-67-C1

Description

The system shall supply air on its own without need of the air supply unit being connected.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.2 Medical Air

Requirement Type Functional

ID SyOPS-67-C2

Description

The system shall have an internal blower that can contiue the operation when medical air is not supplied or run without the need of medical air.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.3 Air Mix

Requirement Type Functional

ID SyOPS-67-C3

Description

The system shal be capable of micing oxygen into the ambient airflow.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.4 Blower Peak Flow

Requirement Type Functional

ID SyOPS-67-C4

Description

The system shall be capable of delievering a maximum of 160L/min of mixed air with compensation for leakage.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.5 Pressure

Requirement Type Functional

ID SyOPS-67-C5

Description

The system shall be capable of delievering the flow rate at the set pressure from the control system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.6 Normal Use Range

Requirement Type Functional

ID SyOPS-67-C6

Description

The normal use range of the system shall be capable of operating without failure betweeen 80 to 100L/min.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.7 Noise

Requirement Type Functional

ID SyOPS-67-C7

Description

The system shall operate between 80 to 100L/min with a noise level of 35dBA (or lower) at a distance of one meter.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.8 Flow Rate

Requirement Type Functional

ID SyOPS-67-C8

Description

The system shall be capable of providing a flow rate of 80 to 260 L/min to compensate for air leakages.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.9 Turbine high flow rate

Requirement Type Functional

ID SyOPS-67-C9

Description

The system shall have a turbine that does not limit at 260L/min to avoid wearout.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.10 Flow Genarator

Requirement Type Functional

ID SyOPS-67-C10

Description

The system shall utilise a software signal flow genarator to manipulate air flow.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.11 No Medical Air

Requirement Type Functional

ID SyOPS-67-C11

Description

The system shall function in the absence of medical air.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.12 Dual System

Requirement Type Functional

ID SyOPS-67-C12

Description

The system shall be able to supply air and gas.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.13 Ambient Air Inlet

Requirement Type Functional

ID SyOPS-67-C13

Description

The system shall filter the ambient air inlet such no impuraties can enter the patients air ways.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

6.14 Oxygen Addition

Requirement Type Functional

ID SyOPS-67-C14

Description

The system shall add oxygen within the air suply unit.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7 Patient Subsystem Provide BiPAP air

Requirement Type Functional

ID SyOPS-68

Description

The Patient Interface Sub-system shall be capable of providing BiPAP air to the patient.

Change Information [Change issue detected.](#ChangedLinkListTable)

Links

Artifact: [BiPAP\_Architecture.slx](#ArtifactListTable)

|  |  |
| --- | --- |
| Linked Item | Link Type |
| BiPAP\_Architecture:39 | Implemented by |

Implementation Status

Total: 26, Implemented: 1, Justified: 0, None: 25

Verification Status

Total: 26, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 26

7.1 Oxygen Nasal Inlet

Requirement Type Functional

ID SyOPS-68-C1

Description

The system shall allow for the patient mask for nasal oxygen inlet.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.2 Pressure Suplied

Requirement Type Functional

ID SyOPS-68-C2

Description

The system patient interface shall allow for pressure of 200-500Kpa (NVP 1.3)

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.3 Hose

Requirement Type Functional

ID SyOPS-68-C3

Description

The hose from the system shall have a three meter long hose that can withstand the pressure.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.4 Oxygen Outlet

Requirement Type Functional

ID SyOPS-68-C4

Description

The system shall be able to connect to the standard (South African 2021) wall outlet cylinder.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.5 Air Switch

Requirement Type Functional

ID SyOPS-68-C5

Description

The system shall be capable of switching from hosital supplied medical air and turbine supplied ambient air.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.6 Gas Connectors and Hoses

Requirement Type Functional

ID SyOPS-68-C6

Description

The system shall abide by ISO7396-1:2016 medical gas pipeline systems-Part 1: Pipeline systems for compressed medical gases and vacuum.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.7 Outlet and Probes

Requirement Type Functional

ID SyOPS-68-C7

Description

The system shall abide to SANS 1409:2014 Outlet sockets and probes for medical (gas and vacuum) services used in hospitals,

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.8 Cones and Sockets

Requirement Type Functional

ID SyOPS-68-C8

Description

The system shall abide by ISO: 5356-1:2015 Anaesthetic and respository equipment - Conical connectors- Part 1: Cones and sockets

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.9 Breathing Gas Pathway

Requirement Type Functional

ID SyOPS-68-C9

Description

the system shall allow for the assembling of the breathing gas pathway, including connection of the detachable parts of the gas pathway to the air supply subsystem

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.10 Humidifier Attach

Requirement Type Functional

ID SyOPS-68-C10

Description

The system shall have the capability of connecting of a humidifier to the patient interface as an external system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.11 Mask Size

Requirement Type Functional

ID SyOPS-68-C11

Description

The system shall make use of a full face mask or half face mask.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.12 Mask Comfert

Requirement Type Functional

ID SyOPS-68-C12

Description

The system shall have a mask that mitigates chances of sores when resting on the patients face.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.13 Humidifier

Requirement Type Functional

ID SyOPS-68-C13

Description

The system shall when humidifying via external meas humidify by the inspired gas actively (servo controlled heated humidifier) or heat and moisture exchange filyer (HMEF) at the patient interface (NVP F.8.1).

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.14 External Humidifier

Requirement Type Functional

ID SyOPS-68-C14

Description

The system shall allow for the addition of a humidifier on the patient interfce and not an internal humidifier.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.15 Bacteria Filter

Requirement Type Functional

ID SyOPS-68-C15

Description

The system shall have a bacterial filter in the patient interface.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.16 Nasal Mask

Requirement Type Functional

ID SyOPS-68-C16

Description

The system shall be provided with a nasal mask for adult abd paediatric with relavaent tubing.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.17 Oral Mask

Requirement Type Functional

ID SyOPS-68-C17

Description

The system shall provide a oral mask for adult and paediatric.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.18 Single Use

Requirement Type Functional

ID SyOPS-68-C18

Description

The instraments that come into contact with the patient will be treated as single use consumables and other elements shall be able to withstand harsh disinfectant chemicals.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.19 Harmful Consumable

Requirement Type Functional

ID SyOPS-68-C19

Description

The system shall avoid or account for consumables that may cause additional damage to the patient.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.20 Manditory filter

Requirement Type Functional

ID SyOPS-68-C20

Description

The system shall have a manditory bacteria filter with reusable accessories.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.21 Nasal Mask Clean

Requirement Type Functional

ID SyOPS-68-C21

Description

The system shall utilise adult and paediatric nasal mask and tubing that can be cleaned with high level disinfectants and sterilization.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.22 Oral Mask Clean

Requirement Type Functional

ID SyOPS-68-C22

Description

The system shall utilise adult and paediatric oral mask and tubing that can be cleaned with high level disinfectants and sterilization.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.23 Helmet Clean

Requirement Type Functional

ID SyOPS-68-C23

Description

The system shall utilise adult and paediatric helmet and tubing that can be cleaned with high level disinfectants and sterilization.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.24 Connectors

Requirement Type Functional

ID SyOPS-68-C24

Description

The system shall allow for connectors for air and oxygen outlets, asaptable for most connectors including barb, NF, DISS and NIST.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

7.25 Hose Clamp

Requirement Type Functional

ID SyOPS-68-C25

Description

The system shall include a hose clamp that keep hose secured to the system.

Change Information No change issue detected.

Implementation Status

Total: 1, Implemented: 0, Justified: 0, None: 1

Verification Status

Total: 1, Passed: 0, Justified: 0, Failed: 0, Unexecuted: 0, None: 1

Appendix

Artifact List

Simulink Requirement Set files:

|  |  |  |  |
| --- | --- | --- | --- |
| # | Name | Folder | Revision |
| 1 | URS.slreqx | C:\CSN Projects\Virovent\Matlab\Actual Supository | 4 |

Simulink models:

|  |  |  |  |
| --- | --- | --- | --- |
| # | Name | Folder | Version |
| 1 | BiPAP\_Architecture.slx | C:\CSN Projects\Virovent\Matlab\Actual Supository | Unloaded. |