Manufacturing Test Specification
Volume and Pressure Tests
PB560

Revision History

Revision	Change Order	Author	Approval by	Approval Date	Summary of Change
X1	ECO-R178940	[redacted]	See Agile	See Agile	Initial Draft Release
A	ECO-R182740	[redacted]	See Agile	See Agile	Release to Rev A
B	RC182139	[redacted]	See Agile	See Agile	Update test limits for monitored PEEP, monitored PiP from +/-(2+8%) to +/-(2+4%) to align with new Homecare standard EN 80601-2-72:2015 Clause 201.12.4.102. Update Safety Pressure upper limit from 60 to 90 to match change per SCR195 CDP-00014971 which has been made to align with Homecare Standard EN 80601-2-72:2015 Clause 201.12.4.105.

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1. SCOPE

This manufacturing test specification document defines the PB560 volume and pressure tests for final system testing referenced in the PB560 Final System Test Doc P/N 10039304.

2. APPLICABLE DOCUMENTS

The test specification is developed with reference to the appropriate issue of the following documents at the time of this document preparation.

[1] PB560 Product Requirements Doc (PRD) P/N 10035480

[2] PB560 Final System Test Doc P/N10039304

[3] Turbine Box Hardware Specification, PB 540 P/N 10025027

[4] CPU Software Requirements Specification, PB560 P/N 10037185

3.DEFINITIONS

BPM or RESP RATE	-	Breaths per Minute
PEEP	-	Positive End Expiratory Pressure
PIP	-	Peak Inspiratory Pressure: Maximum pressure during Inspiration
TE	-	Computed Expiratory time
TI	-	Computed Inspiratory time
VTI	-	Inspiratory Tidal Volume
VTE	-	Exhalation Tidal Volume
UUT	-	Unit Under Test

4. INTRODUCTION

The following volume and pressure tests defined are for the PB560 Final System Test. To cover the full range of volume and pressure tests a pediatric and adult test lung and patient circuit are used, see Ref [2] document.

5. PEDIATRIC TESTS

The following tests are performed with the pediatric test lung and pediatric patient circuit. The table below indicates the test lung and vent settings. The alarm states possible are 0 = inactive, 1 = Detected, 2 = True, 3 = Display. Each test setting checks the High Pressure and Low Pressure Disconnection Alarm for a state of 0 to 1, except the 400mL test setting which checks that the High Pressure Alarm is at a Display state of 3.

Volume Tests

Vti Setting (mL)	Compl/Res Test Lung wCircuit	PEEP	R-Rate	Insp Time(S)	Inspiratory Sens	Ramp
50	C3/Rp50/ped	0	30	0.7	5	D
400 Note1	C3/Rp50/ped	0	15	1.5	5	D

Note 1: The 400mL Vti setting is for the Safety Pressure Test – See Section 8

Pressure Tests

P Control Setting	PEEP Setting	PIP (cmH2O)	Rise Time	R-Rate	Inspiratory Time (S)	Inspiratory Sens
10	0	**10**	2	15	1.5	5
5	5	**10**	2	15	1.5	5

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6. ADULT TESTS

The following tests are performed with the adult test lung and adult patient circuit. The table below indicates the test lung and vent settings.

The alarm states possible are 0 = inactive, 1 = Detected, 2 = True, 3 = Display. Each test setting checks the High Pressure and Low Pressure Disconnection Alarm for a state of 0 to 1.

Volume Tests

Vti Setting (mL)	Compl/Res Test Lung wCircuit	PEEP	R-Rate	Insp Time(S)	Inp Sens	Ramp
500	50/Rp5/adult	0	15	1.3	5	D
900	50/Rp5/adult	0	15	1.3	5	D
1500	50/Rp5/adult	0	15	1.3	5	D
2000	50/Rp5/adult	0	15	1.3	5	D

Pressure Tests

P Control Setting	PEEP Setting	PIP (cmH2O)	Rise Time	R-Rate	Insp Time (S)	Inp Sens
15	5	**20**	2	15	1.5	5
35	5	**40**	2	15	1.5	5
35	20	**55**	2	5	6	5

7. VOLUME TEST

The following tests are performed for each volume measurement test specified in the Pediatric and Adult tests in Sections 5 and 6, excluding specific tests as in the Safety Pressure Test in the Pediatric tests. Each test is to compare vent setting value or vent measured value with the measurement instrument. For the alarms tests, the vent alarm state value is checked with a constant value.

Test	Final Test Limit	PRD Reference
Compare the Volume Control Setting to the Measurement Instrument VTI reading	±(10%+10mL)	PRD129a
Compare the Resp Rate Setting to the Measurement Instrument RESP RATE reading	± 1 bpm	PRD131
Compare the PEEP Setting to the Measurement Instrument PEEP reading . Note: When PEEP is OFF or 0 the tolerance is 1.5cmH2O	±(10%+1cmH2O)	PRD128
Compare the TI CONTROL Setting to the Measurement Instrument TI reading	±10%	PRD124
Compare the Vent Measured VTI to the Measurement Instrument VTI reading	±(10%+10mL)	PRD142a
Compare the Vent Measured VTE to the Instrument VTI reading	±(10% +10mL)	PRD143a
Compare the Vent Measured Resp Rate to the Measurement Instrument RATE reading	± 1 bpm	PRD135
Compare the Vent Measured PIP to the Measurement Instrument PMAX reading	±(4%+2cmH2O)	PRD140a
Compare the Vent Measured PEEP to Measurement Instrument PEEP reading . Note: When PEEP is OFF or 0 the tolerance is 1.5cmH2O	±(4%+2cmH2O)	PRD139a
Compare the Vent Measured TI/TE to the Measurement Instrument TI/TE reading	±10%	PRD146
Check the Vent ALARMS_ALARM_HIGH_PRESSURE alarm to be inactive (state = 0) or Detected (state = 1). Exception: Pediatric Safety Pressure (400mL Volume) Test – see Section 8.	Alarm state = 0 to 1	PRD176
Check the Vent ALARMS_ALARM_DISCONNECTION alarm to be inactive (state = 0) or Detected (state = 1)	Alarm state = 0 to 1	PRD174

8. PRESSURE TEST

The following tests are performed for each pressure measurement test specified in the Pediatric and Adult tests. Each test is to compare vent setting value or vent measured value with the measurement instrument. For the alarms tests, the vent alarm state value is checked with a constant value.

Test	Final Test Limit	PRD/SRS Reference
Compare the Resp Rate Setting to the Measurement Instrument RESP RATE reading	± 1 bpm	PRD131
Compare the PEEP Setting to the Measurement Instrument PEEP reading. Note: When PEEP is OFF or 0 the tolerance is 1.5cmH2O	±(10% +1cmH2O)	PRD128
Compare the P CONTROL + PEEP Setting to the Measurement Instrument PPLAT reading	±(10% +1cmH2O)	PRD126
Compare the TI CONTROL Setting to the Measurement Instrument TI reading	±10%	PRD124
Compare the Vent Measured Resp Rate to the Measurement Instrument RATE reading	± 1 bpm	PRD135
Compare the Vent Measured PIP to the Measurement Instrument PMAX reading	±(4% +2cmH2O)	PRD140a
Compare the Vent Measured PEEP to the Measurement Instrument PEEP reading. Note: When PEEP is OFF or 0 the tolerance is 1.5cmH2O	±(4% +2cmH2O)	PRD139a
Compare the Vent Measured TI/TE to the Measurement Instrument TI/TE reading	±10%	PRD146
Compare the Vent Measured Exh Valve Pressure to the Measurement Instrument PMAX reading (Adult tests)	±(4% +2cmH2O)	PRD140a
Check the Vent ALARMS_ALARM_HIGH_PRESSURE alarm to be inactive (state = 0) or Detected (state = 1)	Alarm state = 0 to 1	PRD176
Check the Vent ALARMS_ALARM_DISCONNECTION alarm to be inactive (state = 0) or Detected (state = 1)	Alarm state = 0 to 1	PRD174
High Pressure Alarm Test - Check the Vent ALARMS_ALARM_ HIGH_PRESSURE alarm to be active (display state = 3) when vent is setup to create a patient pressure exceeding 60 cmH2O. *Note: Per PRD107a, High PiP alarm setting can be set from 12 to 90 cmH2O. The detection of the alarm depends on pressure sensor readings; the software limitation following detection are constant no matter what the setting. Demonstrating a pass at a setting of 60 shall cover the full range.*	Alarm state = 3	PRD107a, PRD176

Safety Pressure Test (Pediatric) - check the vent patient pressure (max) to be within the test limit when the vent is setup to when the vent is setup to achieve max pressure. *This checks the Maximum Pressure limitation for the vent. The max pressure is limited either by the maximum capability of the blower or by the limit hard-coded in the product software as per software requirement SFSFST11.2. (90 cmH2O limit with additional margin of 4 cmH2O allowed for 200ms timing). Lower limit is set to match minimum Blower pressure capability specification (per 10025027).*	70 to 94 cmH2O	SFSYST11.2 HMTUB5