

BIOVALVE™ TEST REPORT



Contents

Page	Section	Heading/Title
2	1	Purpose
2	2	Background
2	3	Summary
2	4	Scope
2	5	References
2	6	Equipment and Materials
3	7	Results
5	8	Data Analysis
9	9	Schedule and Personnel
9	10	Material Disposition

Bio Pure
Technology Ltd

7 Falcon Court
Parklands Business Park
Denmead
Hampshire
PO7 6BZ

Tel: 023 9249 9000
Fax: 023 9249 9001
Email: sales@biopuretech.com
Web: www.biopuretech.com

1. Purpose

To conduct pressure and torque testing of the Bio Valves™ as specified in the Bio Valve™ Testing Protocol (TR2070001) and report the findings.

2. Background

We have undertaken non destructive & destructive testing of the Bio Valves™ in large & small sizes from three (3) separate batches.

- Batch 1 were Virgin Valves
- Batch 2 were Autoclaved at 135 °C for 30 minutes
- Batch 3 was Gamma Irradiated between 25kGy – 40 kGy.

All Valves from batches 1 – 3 were from the same batch of moulded Bio Valves™. A series of tests designed to simulate and exceed normal operating conditions is to be undertaken to compare the effects of Gamma Irradiation and Autoclaving on the performance of the Bio Valves™. The (in – use) durability and robustness of the Bio Valves™ both before and after sterilization by Gamma Irradiation and Steam Autoclaving will be tested.

3. Summary

The testing was conducted as per the Bio Valve™ Testing Protocol - TR2070001 Issue 1. A total of 270 different tests were evaluated by means of pressure testing, heating & pressure testing and torque testing. Both large and small Valves from batches 1 - 3 passed all the tests and the acceptance criteria recorded in the Bio Valve Testing Protocol.

4. Scope

The scope of work was to:

- Conduct tests on the Bio Valves™ as per the Bio Valve™ Testing Protocol (TR2070001 Issue 1)
- Analyse test results
- Report the findings

5. References

Item #	Document	Reference
1	Valve Testing Protocol	TR2077001 Issue 1

6. Equipment and Materials

The equipment required for the Bio Valve™ testing are listed in table 7.1

Item #	Test Equipment	Reference
1	Dial Torque Wrench	0133
2	Pressure Test Equipment	0134
3	Electric Heating Cabinet	0135
4	½" Braid Reinforced Silicone Tubing	STHT-R-0500
5	1" Braid Reinforced Silicone Tubing	STHT-R-1000

Table 7.1 – Bio Valve™ Test Equipment

Materials required for the Bio Valve testing are listed in table 7.2

Item	Description	Part No.	Batch No.
Small Bio Valve	Virgin Bio Valve	MA-900-0138	WOAB0401
Large Bio Valve	Virgin Bio Valve	MA-900-0139	WOAB0402
Small Bio Valve	Autoclaved Bio Valve	MA-900-0138	WOAB0401
Large Bio Valve	Autoclaved Bio Valve	MA-900-0139	WOAB0402
Small Bio Valve	Gamma Irradiated Bio Valve	MA-900-0138	WOAB0401
Large Bio Valve	Gamma Irradiated Bio Valve	MA-900-0139	WOAB0402

Table 7.2 – Bio Valve™ Test Materials

7. Results

Each batch was subjected to the same testing under controlled conditions as per the Bio Valve™ Testing Protocol.

Batches 1 - 3 consisted of 2 sizes of Valve, 15 samples per size.

	Test 1. Pressure Test	Test 2. Heat & Pressure Test	Test 3. Handle Torque Test
Batch 1. Virgin Valves	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests
Batch 2. Autoclaved Valves	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests
Batch 3. Gamma Irradiated Valves	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests	2 Sizes of Valve 15 Samples per size 2 x 15 = 30 Tests
Total No. of Tests = 270			

Table 7.1 – Test Matrix

Test 1

Upon visual examination of batches 1 – 3 no leaks were observed from the clamped Braid Reinforced Silicone Tubing in both sizes of Bio Valve™. The pressure drop was recorded over a 30 second period once the system had stabilised. This varied between 15 to 60 seconds per Valve. The Bio Valve™ /

Braid Reinforced Silicone Tubing union was pressurised to 4.48Bar when using the large Bio Valves™ and 9.65 Bar when using the small Bio Valves™.

They were pressurised using water. Due to the nature of the testing and the equipment utilised there is a degree of system pressure creep in the set up as the water (and air pockets) under pressure can cause the flexible tubing to expand over prolonged periods causing a slight pressure drop.

However, the pressure drop recorded was no more than 0.02 Bar. (This could be a leak from the Bio Valve™ or from the system, although no evidence of water seepage was seen on any of the tests) The accuracy of the digital pressure gauge is 0.01Bar. The changes in pressure recorded over the 30 second period were deemed acceptable for the testing being carried out and the equipment being used. All Bio Valves™ were torque tightened to 2.5Nm.

Test 2

Upon visual examination of batches 1 – 3 no leaks were observed from the clamped Braid Reinforced Silicone Tubing in both sizes of Bio Valve™. The pressure drop was recorded over a 30 second period once the system had stabilised. This varied between 15 to 60 seconds per Valve. The Bio Valve™ /

Braid Reinforced Silicone Tubing union was pressurised to 4.48Bar when using the large Bio Valves™ and 9.65 Bar when using the small Bio Valves™.

They were pressurised using water. Due to the nature of the testing and the equipment utilised there is a degree of system pressure creep in the set up as the water (and air pockets) under pressure can cause the flexible tubing to expand over prolonged periods causing a slight pressure drop.

However, the pressure drop recorded was no more than 0.02 Bar. (This could be a leak from the Bio Valve™ or from the system, although no evidence of water seepage was seen on any of the tests) The accuracy of the digital pressure gauge is 0.01Bar. The changes in pressure recorded over the 30 second period were deemed acceptable for the testing being carried out and the equipment being used. All Bio Valves™ were torque tightened to 2.5Nm.

Test 3

All Bio Valves™ in the small size from batches 1 – 3 displayed an average torque value at the point of failure of between 5.5 Nm and 10 Nm. All Bio Valves™ in the large size from batches 1 – 3 displayed an average torque value at the point of failure of between 14.5 Nm and 23.5 Nm.

Observations

- Bio Valves™ in both large and small sizes that had been Autoclaved were observed to have lost the smooth screw down action when turning the handle to tighten the valve onto a piece of tube.
- The strength of the Bio Valves™ in the destructive torque test (Test 3) decreased from virgin to sterilized in the case of the large valves but increase in the small valves

Conclusions & Recommendations

- All of the Bio Valves passed the acceptance criteria stated in the Bio Valve™ Testing Protocol
- Visual inspections of all the Bio Valves™ during testing concluded that no leaks of water were visible with the naked eye in tests 1 and 2.
- Pressure changes over a 30 second period are deemed acceptable due the accuracy of the equipment and the inherent system creep associated with the process.
- All destructive handle torque testing of the small Bio Valves™ (Test 3) recorded an absolute minimum result of 5.5 Nm at point of failure across all three batches. The maximum-recorded value was 10 Nm across all three batches.
- All destructive handle torque testing of the large Bio Valves™ (Test 3) recorded an absolute minimum result of 14.5 Nm at point of failure across all three batches. The maximum-recorded value was 23.5 Nm across all three batches.

From all the testing that has been carried out it may be determined that the process of Autoclaving & Gamma Irradiation has no discernable negative effect on the durability and robustness of the Bio Valves™ in both large and small sizes when compared to the un-treated Bio Valves™.

8. Data Analysis

8.1 Test 1 – Pressure Testing Valves at Room Temperature

Valve Type	Valve Size	Average Pressure Drop Over 30 Seconds (Bar)
Virgin Valve	Small	0.0026
Virgin Valve	Large	0.0013
Autoclaved Valve	Small	0.0003
Autoclaved Valve	Large	0.002
Gamma Irradiated Valve	Small	0.002
Gamma Irradiated Valve	Large	0.0013

Table 8.1.1 – Test 1 Results

8.2 Test 2 – Heat & Pressure Testing. Valves at 121 °C

Valve Type	Valve Size	Average Pressure Drop Over 30 Seconds (Bar)
Virgin Valve	Small	0.0053
Virgin Valve	Large	0.0013
Autoclaved Valve	Small	0.0046
Autoclaved Valve	Large	0.0026
Gamma Irradiated Valve	Small	0.004
Gamma Irradiated Valve	Large	0.0013

Table 8.2.1 – Test 1 Results

8.3 Test 3 – 100% Destructive Handle Torque Test

Small Bio Valves™

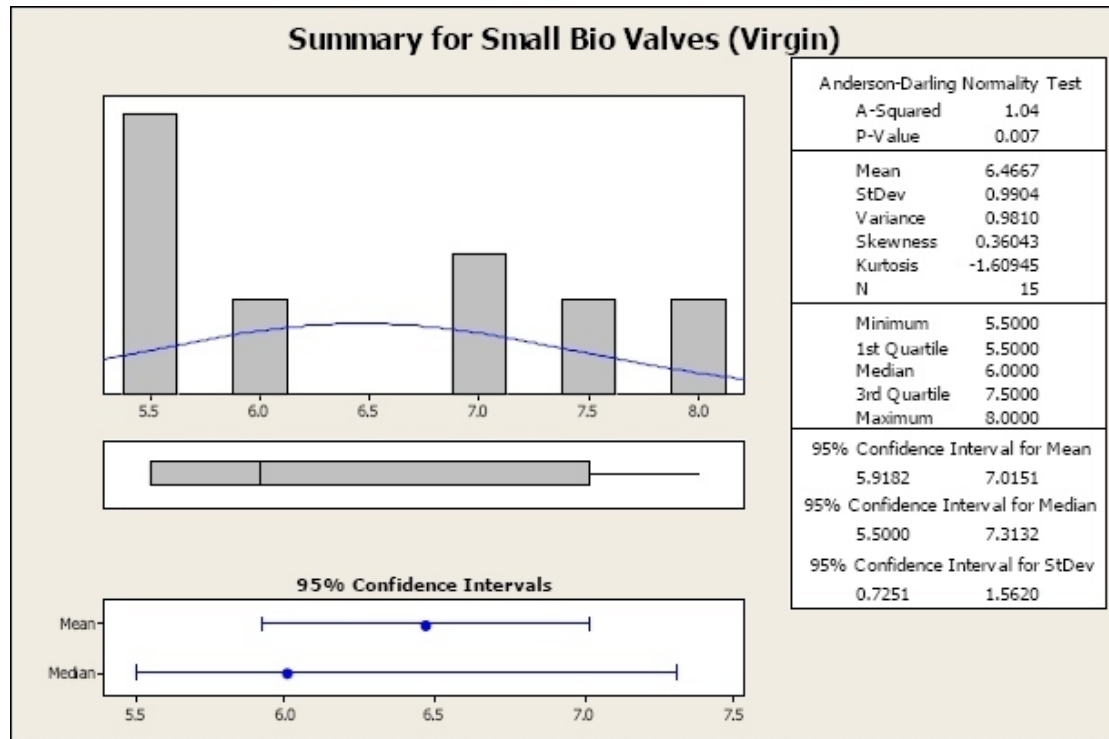


Figure 8.3.1 – Summary of Results for Small Virgin Bio Valve™

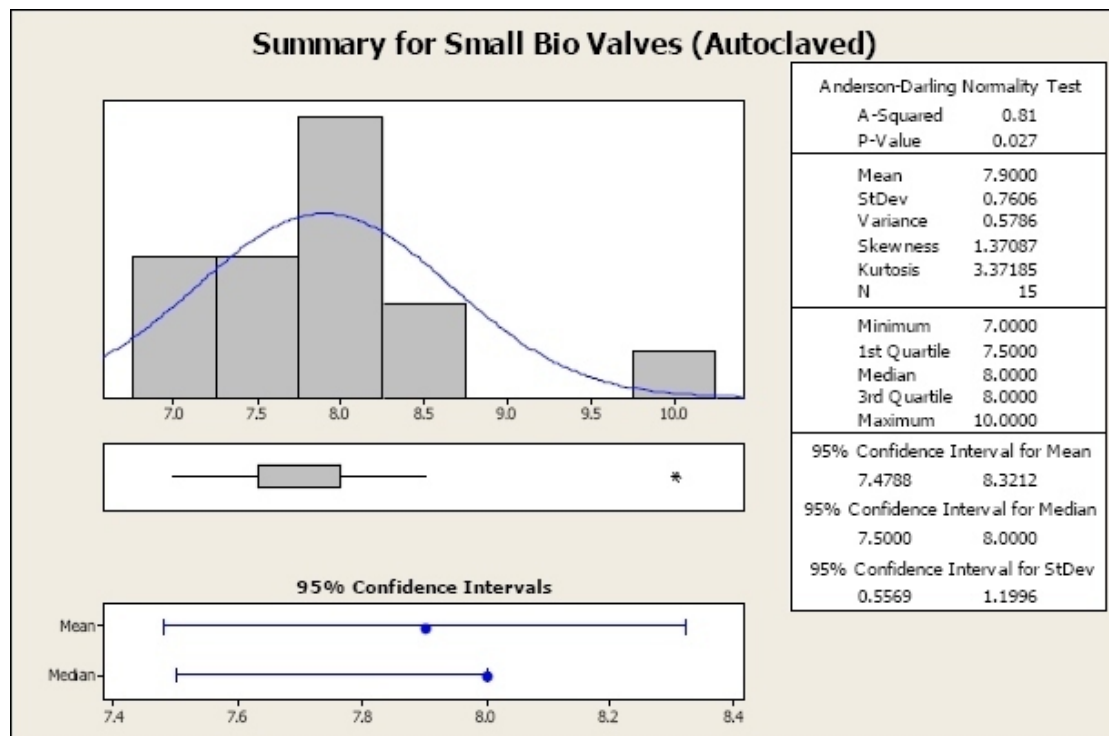


Figure 8.3.2 – Summary of Results for Small Autoclaved Bio Valve™

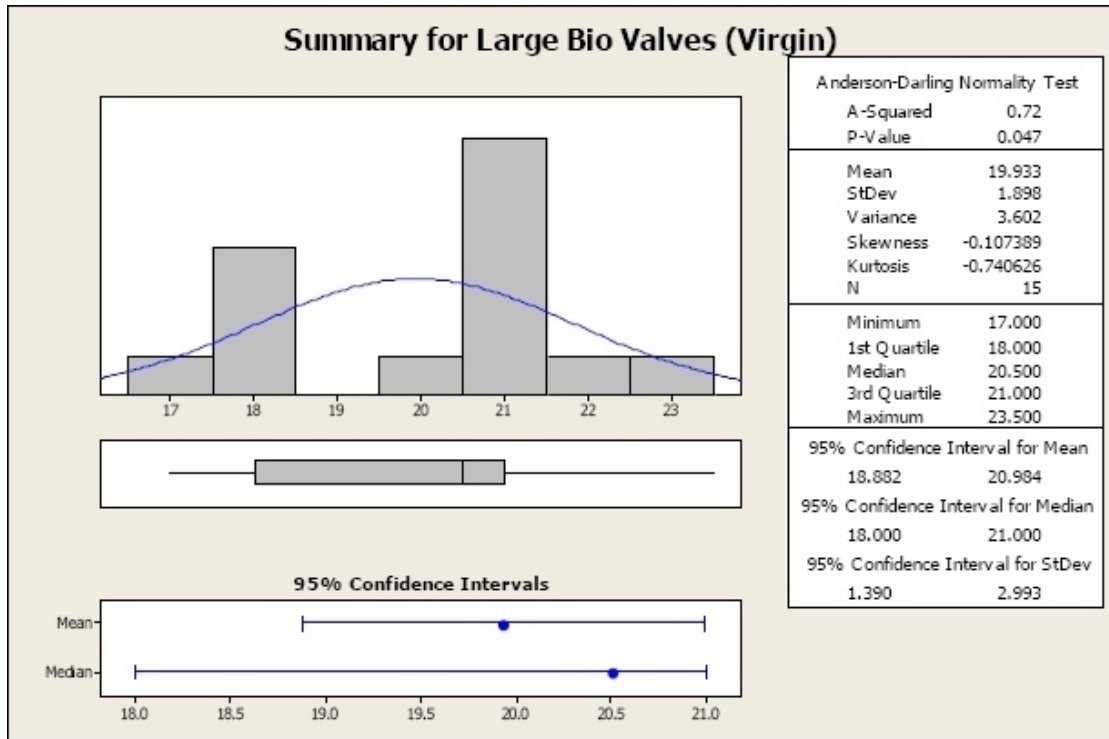


Figure 8.3.3 – Summary of Results for Small Gamma Irradiated Bio Valve™

Large Bio Valves™

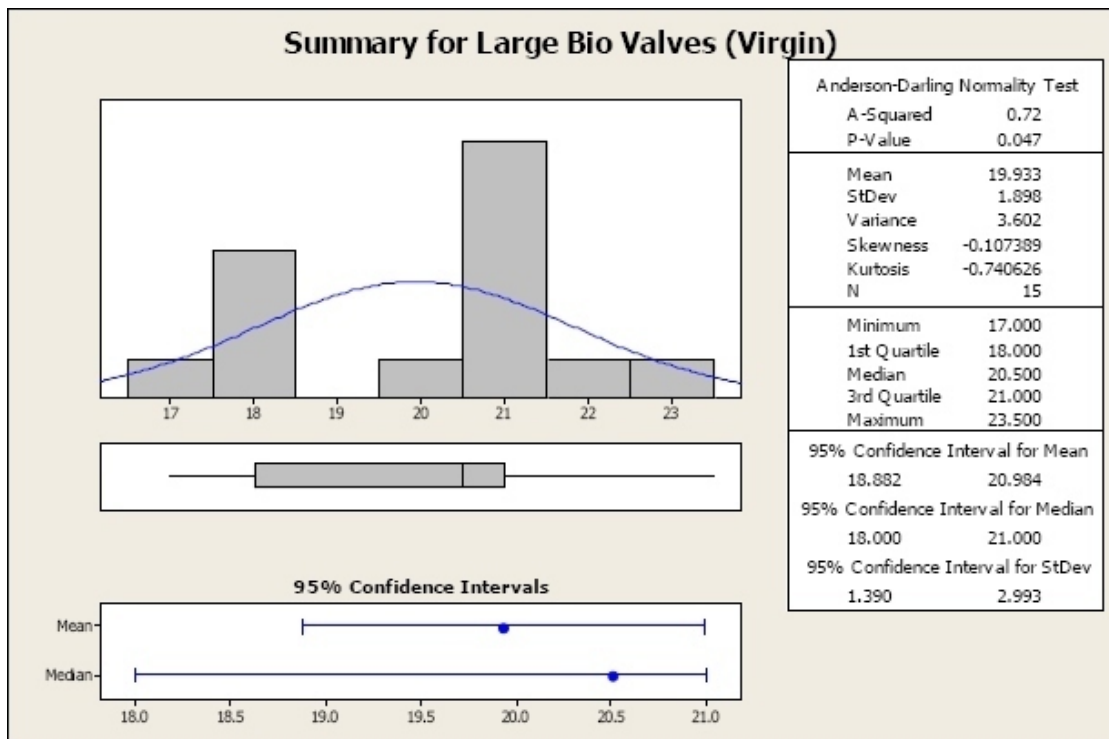


Figure 8.3.4 – Summary of Results for Large Virgin Bio Valve™

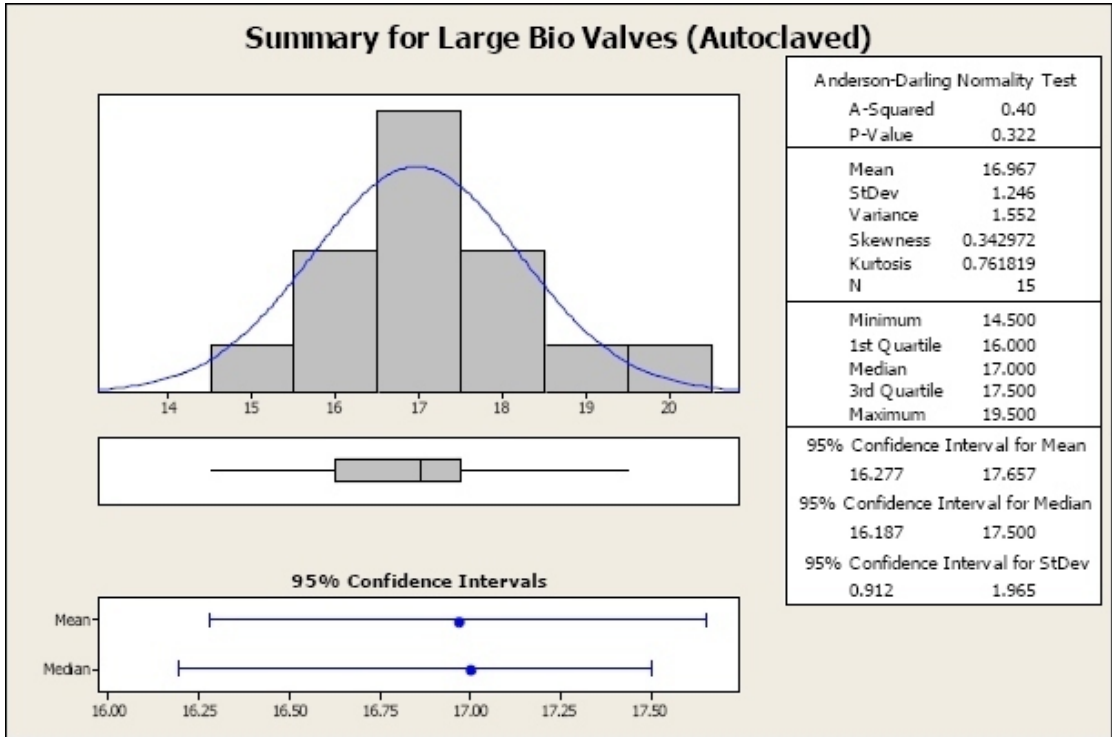


Figure 8.3.5 – Summary of Results for Large Autoclaved Bio Valve™

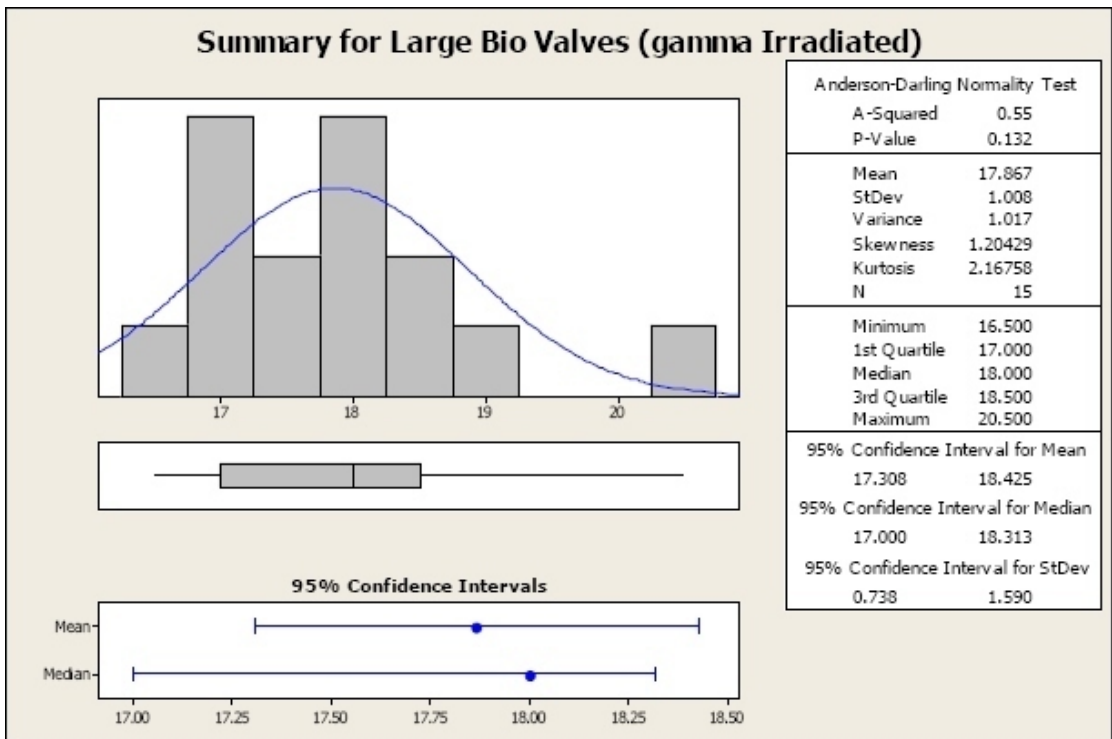


Figure 8.3.6 – Summary of Results for Large Gamma Irradiated Bio Valve™

Summary of Results for Test 3

Valve Type	Valve Size	Mean Average Force at Failure (Nm)
Virgin Valve	Small	6.4667
Virgin Valve	Large	19.933
Autoclaved Valve	Small	7.9
Autoclaved Valve	Large	16.967
Gamma Irradiated Valve	Small	7.8
Gamma Irradiated Valve	Large	17.867

Table 8.3.7 – Summary of Average Forces (Nm) at Failure for Test 3

9. Schedule & Personnel

Ben Harris (Project Engineer) – Pressure testing, Heat & Pressure Testing and Handle Torque Testing

Dave Mitchell (Engineering Technician) – Pressure testing and Heat & Pressure Testing.

10. Material Disposition

All the Bio Valves used in the Tests will committed to land fill.