

BIO CLAMP™ TEST REPORT



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1. Purpose

To conduct pressure and torque testing of the Bio Clamps as specified in the Clamp Testing Protocol (TR2077001) and report the findings.

2. Background

Runfold Medical Ltd (RML) was asked by Bio Pure Technology Ltd to undertake non destructive & destructive testing of the Bio Pure Bio Clamps an all available sizes from three (3) separate batches.

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

All clamps from batches 1 – 3 were from the same batch of moulded Bio Clamps.

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 Clamps. The (in – use) durability and robustness of Bio pure Bio Clamps both before and after sterilization by Gamma Irradiation and Steam Autoclaving will be tested.

3. Summary

The testing was conducted as per the RML Bio Clamp Testing Protocol – TR2077001 Issue 1. A total of 960 different test were evaluated by means of pressure testing, heating & pressure testing, torque testing and by steam testing. Sizes 0.75” to 3.0” clamps from batches 1 - 3 passed all the tests and the acceptance criteria recorded in the Bio Clamp Testing Protocol. The 4.0” Bio Clamps from batches 1 - 3 failed to meet the acceptance criteria for test 2 – The Heat & Pressure Test. Additional 4.0” Clamps were subsequently tested once Bio Pure had made modifications to the design.

These passed all tests and the acceptance criteria recorded in the Bio Clamp Testing Protocol.

4. Scope

The scope of work was to:

- Conduct tests on the Bio Pure Bio Clamps as per the Clamp Testing Protocol (TR2077001 Issue 1)
- Analyse test results.
- Report the findings

5. References

Item #	Document	Runfold Reference
1	Clamp Testing Protocol	TR2077001 Issue 1

6. Equipment and Materials

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

Item #	Test Equipment	Runfold Reference
1	Dial Torque Wrench	0133
2	Pressure Test Equipment	0134
3	Mini Compact Electric Steam Boiler	On Hire
4	Electric Heating Cabinet	0135
5	Temperature Thermocouple	N/A
6	Stainless Steel Sanitary Flanges in sizes 0.75" to 4.0"	On Loan
7	½ armored silicone tubing	On Loan

Table 7.1 – Bio Clamp Test Equipment

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

Item	Description	Part No.	Batch No.
0.75" Bio Clamp	Virgin Bio Clamps	NG075WH	SO8169
1.5" Bio Clamp	Virgin Bio Clamps	NG150WH	SO8169
2.0" Bio Clamp	Virgin Bio Clamps	NG200WH	SO8169
2.5" Bio Clamp	Virgin Bio Clamps	NG250WH	SO8169
3.0" Bio Clamp	Virgin Bio Clamps	NG300WH	SO8169
4.0" Bio Clamp	Virgin Bio Clamps	NG400WH	SO8169
4.0" Bio Clamp	Virgin Bio Clamps	NG400WH	Samples for Test
0.75" Bio Clamp	Autoclaved Bio Clamps	NG075WH	SO8084
1.5" Bio Clamp	Autoclaved Bio Clamps	NG150WH	SO8084
2.0" Bio Clamp	Autoclaved Bio Clamps	NG200WH	SO8084
2.5" Bio Clamp	Autoclaved Bio Clamps	NG250WH	SO8084
3.0" Bio Clamp	Autoclaved Bio Clamps	NG300WH	SO8084
4.0" Bio Clamp	Autoclaved Bio Clamps	NG400WH	SO8084
4.0" Bio Clamp	Autoclaved Bio Clamps	NG400WH	Samples of Test
0.75" Bio Clamp	Gamma Irradiated Bio Clamps	NG075WH	SO8029
1.5" Bio Clamp	Gamma Irradiated Bio Clamps	NG150WH	SO8029
2.0" Bio Clamp	Gamma Irradiated Bio Clamps	NG200WH	SO8029
2.5" Bio Clamp	Gamma Irradiated Bio Clamps	NG250WH	SO8029
3.0" Bio Clamp	Gamma Irradiated Bio Clamps	NG300WH	SO8029
4.0" Bio Clamp	Gamma Irradiated Bio Clamps	NG400WH	SO8029
4.0" Bio Clamp	Gamma Irradiated Bio Clamps	NG400WH	Samples for Test

Table 7.2 – Bio Clamp Test Materials

7. Results

Each batch (1, 2 & 3) plus the additional batch of 4.0" Bio Clamps were subjected to the same testing under controlled conditions as per the Bio Clamp Testing Protocol.

Batches 1 - 3 consisted of 6 sizes of clamp, 15 samples per size, except Test 4, which only used 5 samples in the 1.5" size. Additional testing consisted of 1 size of clamp, 15 samples per size.

See Test Matrix below.

	Test 1. Pressure Test	Test 2. Heat & Pressure Test	Test 3. Handle Torque Test	Test 4. Steam & Pressure Test
Batch 1. Virgin Clamps	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	1 Size of Clamp –1.5” 5 Samples per Size 5 x 1 = 5 Tests
Batch 2. Autoclaved Clamps	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	1 Size of Clamp –1.5” 5 Samples per Size 5 x 1 = 5 Tests
Batch 3. Gamma Irradiated Clamps	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	6 Sizes of Clamp 15 Samples per Size 6 x 15 = 90 Tests	1 Size of Clamp –1.5” 5 Samples per Size 5 x 1 = 5 Tests
Additional Bio Clamps Virgin	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	N/A
Additional Bio Clamps Autoclaved	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	N/A
Additional Bio Clamps Gamma Irradiated	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	1 Size of Clamp (4.0”) 15 Samples per Size 1 x 15 = 15 Tests	N/A
				Total no. of Tests = 960

Table 7.1 – Test Matrix

Test 1

Upon visual examination of batches 1 – 3 and the additional testing of the 4.0” Clamps no leaks were observed from the clamped sanitary flange / gasket union in all 6 sizes of bio clamp. The pressure drop was recorded over a 30 second period once the system had stabilised. This took between 15 to 60 seconds. The Bio Clamp / sanitary flange union was pressurised to 10Bar 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 under 10Bar of pressure heats slightly due the effects of compression. Also there will be a limited amount of flexibility in the tubing used to connect the flanges to the pressure rig.

However, the pressure drop recorded was no more than 0.03 Bar. (This could be a leak from the Bio Clamp 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 Clamps were torque tightened to 2Nm or until the screw thread reached the clamp stops.

Test 2

Upon visual examination of batches 1 - 3 no leaks were observed from the clamped sanitary flange / gasket union for sizes 0.75" to 3.0"

The 4.0" Bio Clamps failed as soon as the system was pressurised to between 5 to 7Bar. It was observed that the gasket was blown out from between the two flanges over a 2 – 3cm length. This happened in the same place each time, next to the Bio Clamp hinge.

Upon re-testing of the additional 4.0" Clamps no leaks were observed from the clamped sanitary flange / gasket union when pressurised to the full 10Bar.

The pressure drop was recorded over a 30 second period once the system had stabilised. This took between 15 to 60 seconds. The Bio Clamp / sanitary flange union was pressurised to 10Bar 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 under 10Bar of pressure heats slightly due the effects of compression. There was also increased heating of the flange and gasket due to the Bio Clamp being heated to 121°C. Also, there will be a limited amount of flexibility in the tubing used to connect the flanges to the pressure rig.

However, the pressure drop recorded was not more than 0.03 Bar. (This could be a leak from the Bio Clamp 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 Clamps were torque tightened to 2Nm or until the screw thread reached the clamp stops.

Test 3

All Bio Clamps in all sizes from batches 1 – 3 and the additional 4.0" clamps displayed an average torque value at the point of failure of between 7Nm and 11Nm.

Test 4

Upon visual examination no leaks were observed from the clamped sanitary flange / gasket union in the 1.5" Bio Clamps that were tested from batches one to three.

The pressure drop was recorded over a 30 second period once the system had stabilised. This took between 15 to 60 seconds. The Bio Clamp / sanitary flange union was pressurised to 10Bar 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 under 10Bar of pressure heats slightly due the effects of compression. There was also increased heating of the flange and gasket due to the system being heated by steam 121°C for a period of 20 minutes. Also there will be a limited amount of flexibility and elasticity in the tubing used to connect the flanges to the pressure rig due to the presence of the steam flowing through the pipe work.

This differs from Test 2 in that the whole pipe system is heated and not just the clamp. However, the pressure drop recorded was again no more than 0.03 Bar. (This could be a leak from the Bio Clamp 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 Clamps were torque tightened to 2Nm or until the screw thread reached the clamp stops, whichever happened first.

Observations

- Bio Clamps from batches 1 – 3 that were heated to 121 °C in the heating cabinet were observed to be a “loose” fit over the sanitary flanges when compared to Bio Clamps at ambient temperature. The material expanding when heated may cause this. All Bio Clamps that were heated would reach the clamp end stops easily and below the 2Nm torque requirement.
- The additional modified 4.0” Bio Clamps were observed to be a better, tighter fit over the sanitary flanges both before and after heating. The Bio Clamps when heated did not reach the clamp end stops as easily as those from batches 1 – 3 when heated.

Conclusions & Recommendations

- All* of the Bio Clamps passed the acceptance criteria stated in the Bio Clamp Testing Protocol for tests 1 to 4.
- Visual inspections of all* the Bio Clamps during testing concluded that no leaks of water were visible with the naked eye in tests 1, 2 & 4.
- 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 when operating at 10Bar.
- All destructive handle torque testing of the Bio Clamps (Test 3) recorded an absolute minimum result of 5Nm at point of failure. The maximum-recorded value was 20 Nm.
- Modifications made to the 4.0” Bio Clamp mould tool eliminated the problems caused by the expansion of the clamp when heated that were experienced in batches 1 – 3.

* This applies to batches 1 – 3 (sizes 0.75” – 3.0”) and the additional 4.0” Bio Clamps. The 15 off 4.0” Bio Clamps from batches 1, 2 & 3 failed Test 2. Upon re-testing with additional modified 4.0” Bio Clamps, test 2 was passed in accordance with the acceptance criteria stated in the Bio Clamp Testing Protocol for test 2.

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 Pure Bio Clamps in sizes from 0.75” to 4.0” when compared to the untreated Bio Clamps.

8. Data Analysis

8.1 Test 1 – Pressure Testing. Clamps at Room Temperature

Clamp Type	Clamp Size	Average Pressure Drop over 30 Seconds (Bar)
Virgin Clamp	0.75”	0.008
Virgin Clamp	1.5”	0.00733
Virgin Clamp	2.0”	0.005333
Virgin Clamp	2.5”	0.004
Virgin Clamp	3.0”	0.007333
Virgin Clamp	4.0”	0.000667

Additional Virgin Clamp	4.0"	0.00867
Autoclaved Clamp	0.75"	0.002667
Autoclaved Clamp	1.5"	0.004
Autoclaved Clamp	2.0"	0.004
Autoclaved Clamp	2.5"	0.005333
Autoclaved Clamp	3.0"	0.002667
Autoclaved Clamp	4.0"	0.000667
Additional Autoclaved Clamp	4.0"	0.01067
Gamma Irradiated Clamp	0.75"	0.004667
Gamma Irradiated Clamp	1.5"	0.006667
Gamma Irradiated Clamp	2.0"	0.003333
Gamma Irradiated Clamp	2.5"	0.001333
Gamma Irradiated Clamp	3.0"	0.002
Gamma Irradiated Clamp	4.0"	0.002667
Additional Gamma Irradiated Clamp	4.0"	0.01067

Table 8.1.1 – Test 1 Results

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

Clamp Type	Clamp Size	Average Pressure Drop over 30 Seconds (Bar)
Virgin Clamp	0.75"	0.008667
Virgin Clamp	1.5"	0.008
Virgin Clamp	2.0"	0
Virgin Clamp	2.5"	0.001333
Virgin Clamp	3.0"	0.000667
Virgin Clamp	4.0"	N/A
Additional Virgin Clamp	4.0"	0.00733
Autoclaved Clamp	0.75"	0.004667
Autoclaved Clamp	1.5"	0.002667
Autoclaved Clamp	2.0"	0.002
Autoclaved Clamp	2.5"	0.006
Autoclaved Clamp	3.0"	0.004
Autoclaved Clamp	4.0"	N/A
Additional Autoclaved Clamp	4.0"	0.00733
Gamma Irradiated Clamp	0.75"	0.002667
Gamma Irradiated Clamp	1.5"	0.003333
Gamma Irradiated Clamp	2.0"	0.002667
Gamma Irradiated Clamp	2.5"	0.000667
Gamma Irradiated Clamp	3.0"	0
Gamma Irradiated Clamp	4.0"	N/A
Additional Gamma Irradiated Clamp	4.0"	0.00533

Table 8.2.1 – Test 2 Results

8.3 Test 3 – 100% Destructive Handle Torque Test

0.75" Bio Clamps

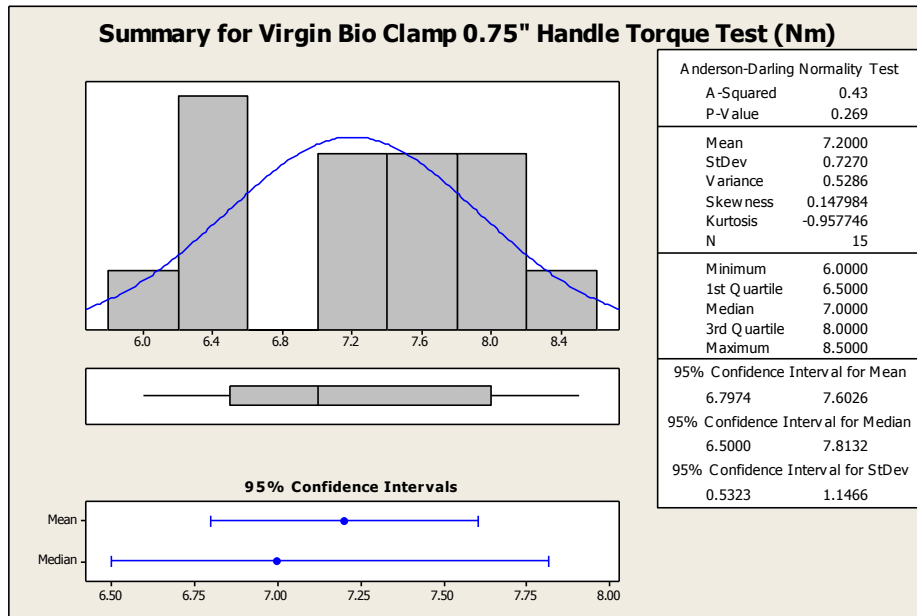


Figure 8.3.1 – Summary of Results for 0.75" Virgin Bio Clamp

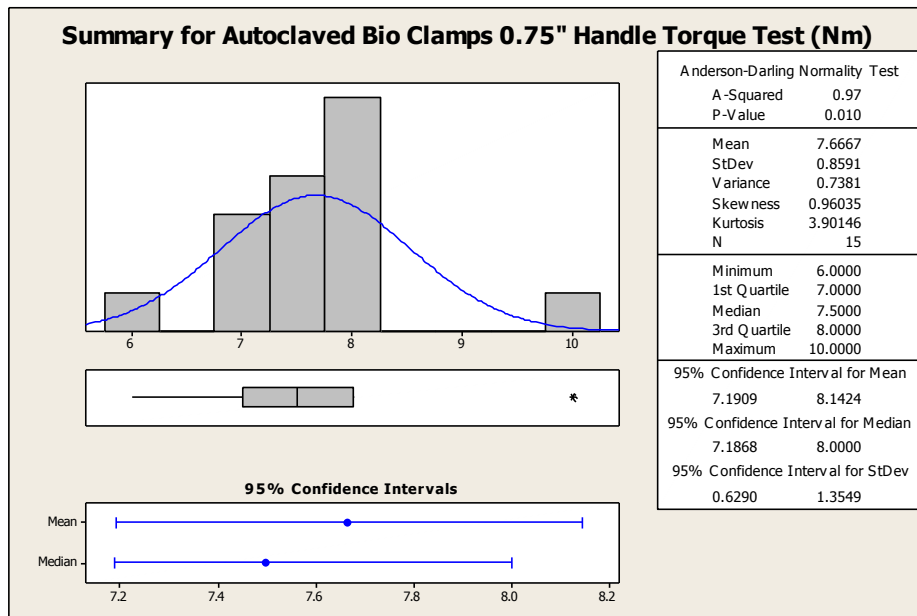


Figure 8.3.2 – Summary of Results for 0.75" Autoclaved Bio Clamp

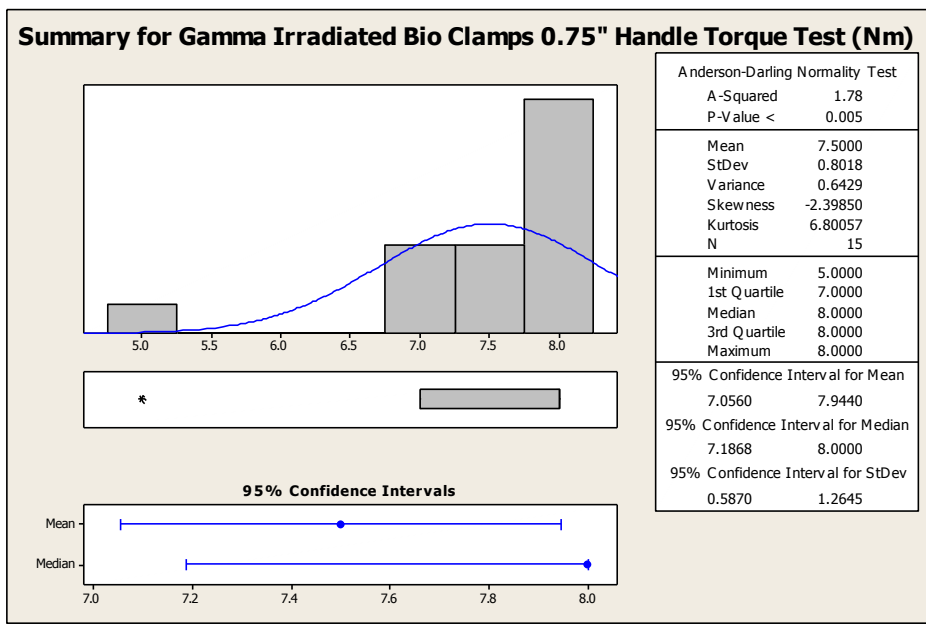


Figure 8.3.3 – Summary of Results for 0.75" Gamma Irradiated Bio Clamp

1.5" Bio Clamps

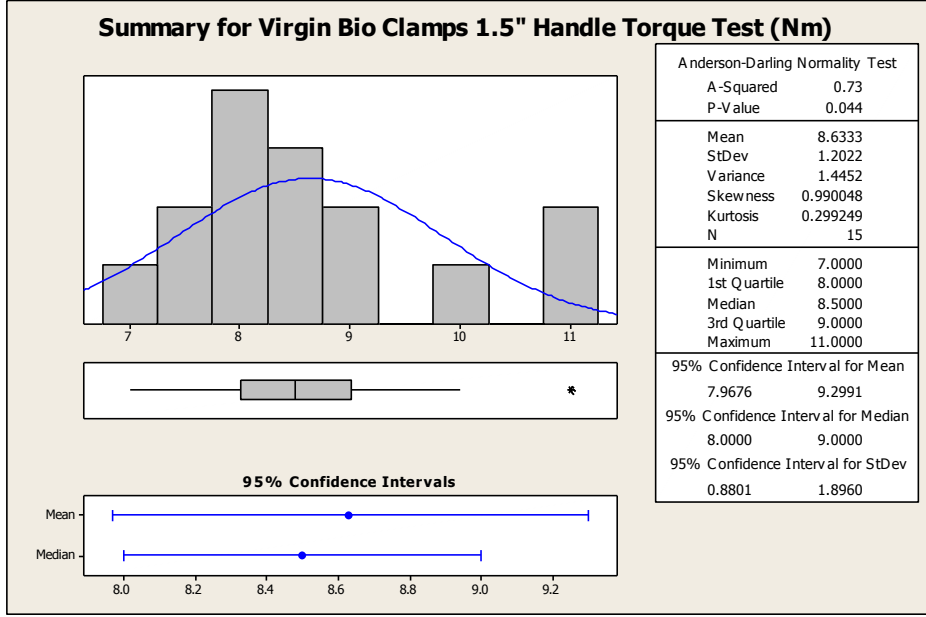


Figure 8.3.4 – Summary of Results for 1.5" Virgin Bio Clamp

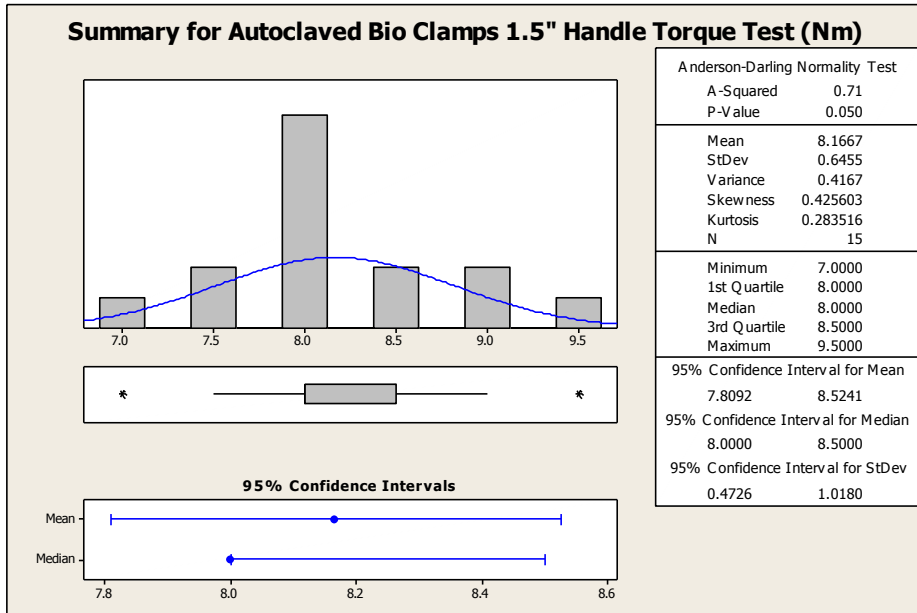


Figure 8.3.5 – Summary of Results for 1.5" Autoclaved Bio Clamp

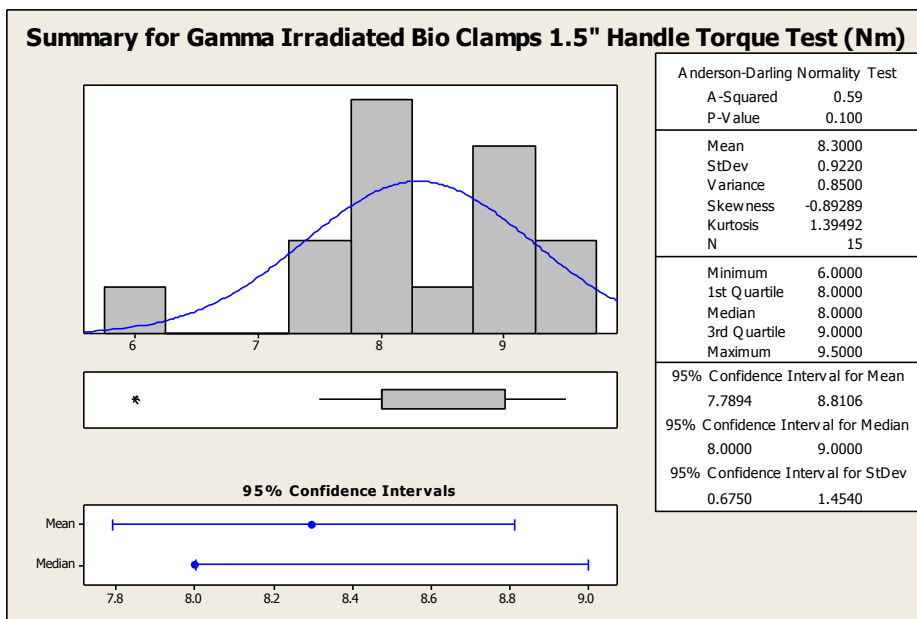


Figure 8.3.6 – Summary of Results for 1.5" Gamma Irradiated Bio Clamp

2.0" Bio Clamps

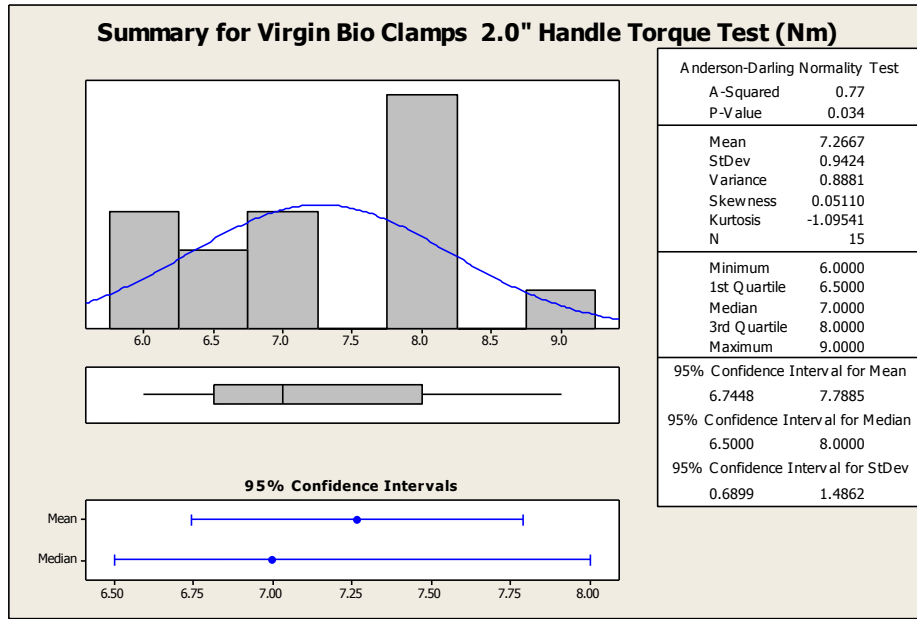


Figure 8.3.7 – Summary of Results for 2.0" Virgin Bio Clamp

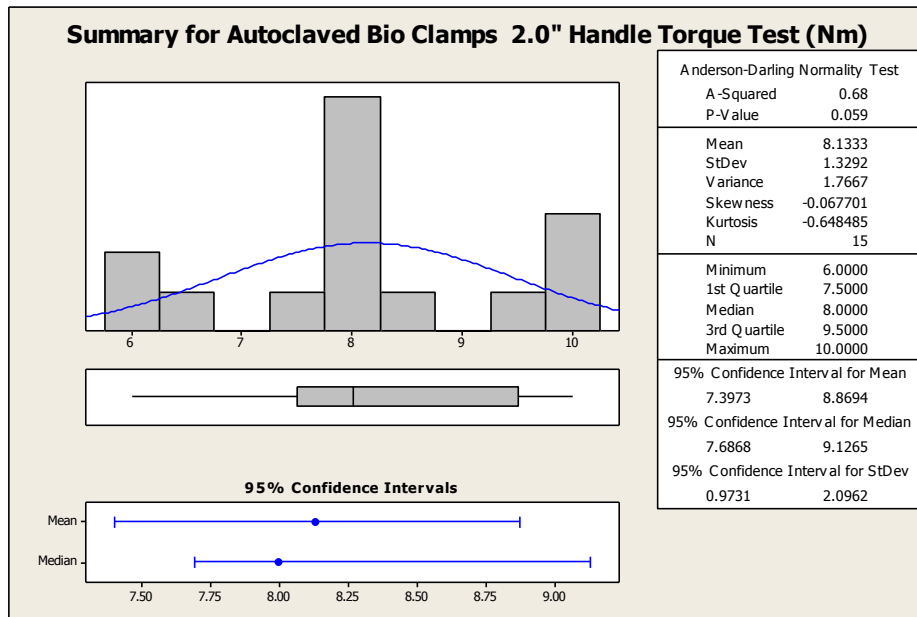


Figure 8.3.8 – Summary of Results for 2.0" Autoclaved Bio Clamp

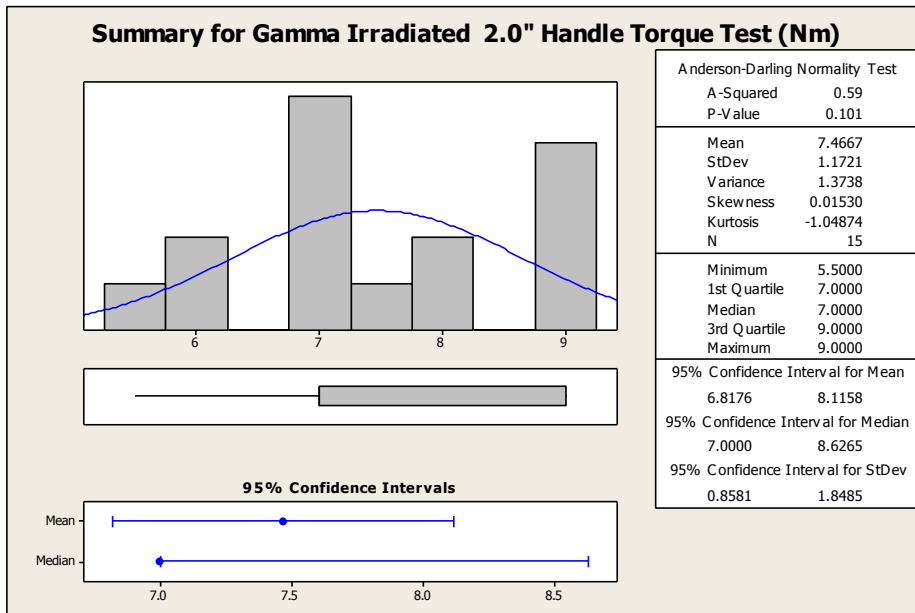


Figure 8.3.9 – Summary of Results for 2.0" Gamma Irradiated Bio Clamp

2.5" Bio Clamps

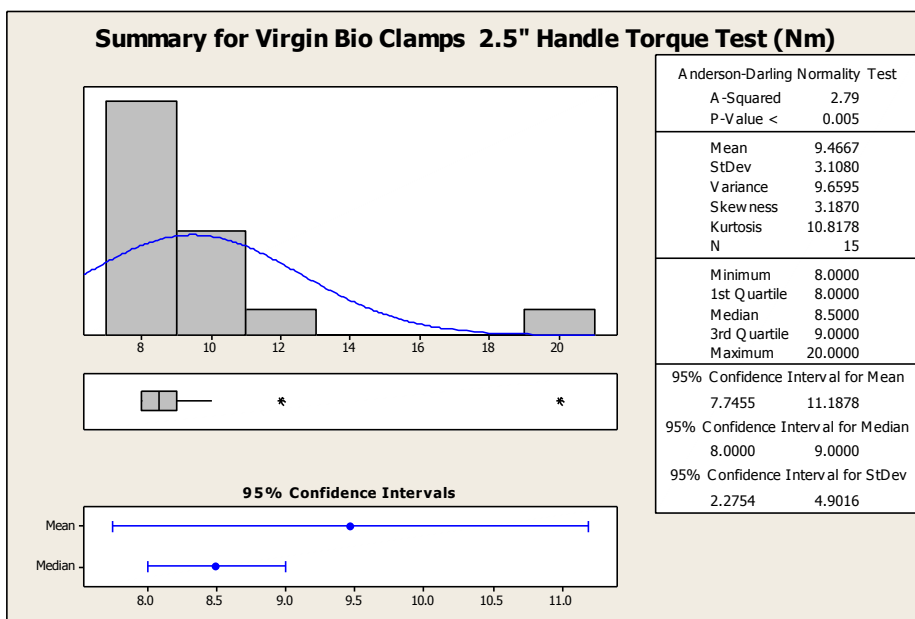


Figure 8.3.10 – Summary of Results for 2.5" Virgin Bio Clamp

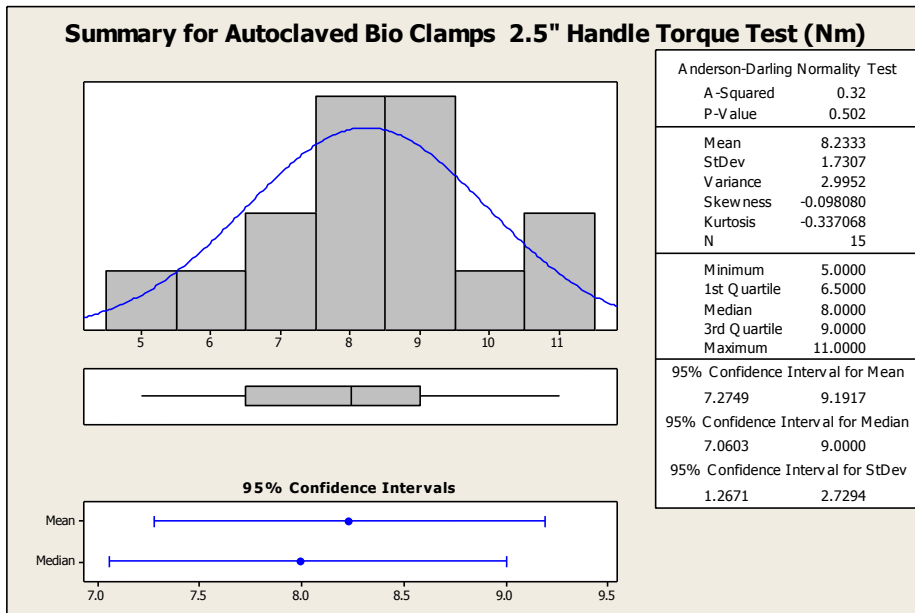


Figure 8.3.11 – Summary of Results for 2.5" Autoclaved Bio Clamp

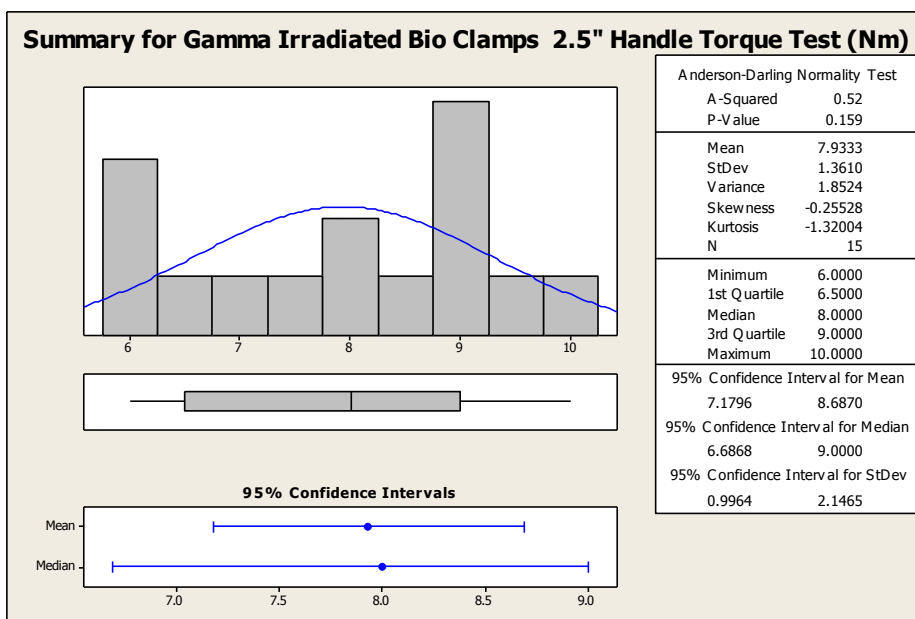


Figure 8.3.12 – Summary of Results for 2.5" Gamma Irradiated Bio Clamp

3.0" Bio Clamps

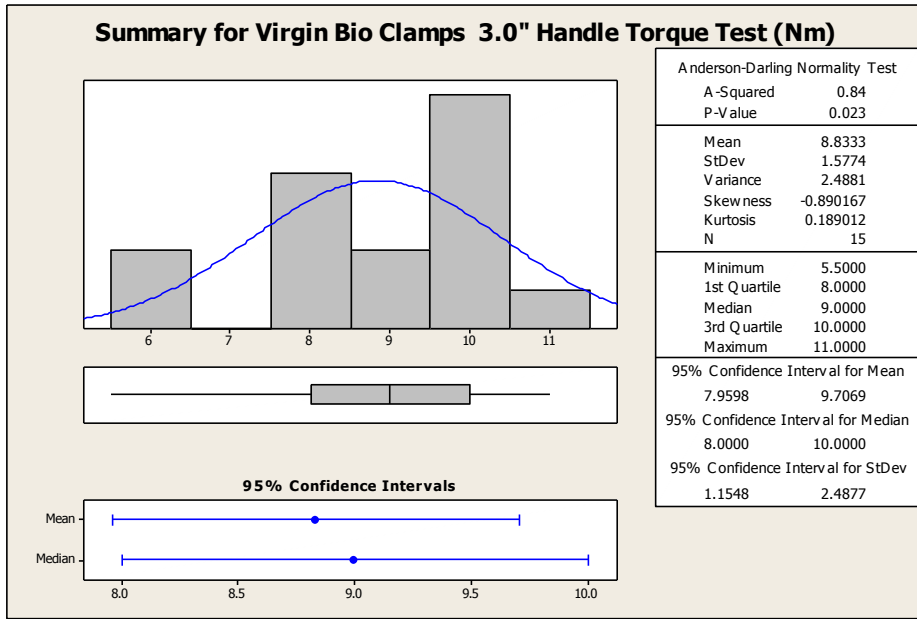


Figure 8.3.13 – Summary of Results for 3.0" Virgin Bio Clamp

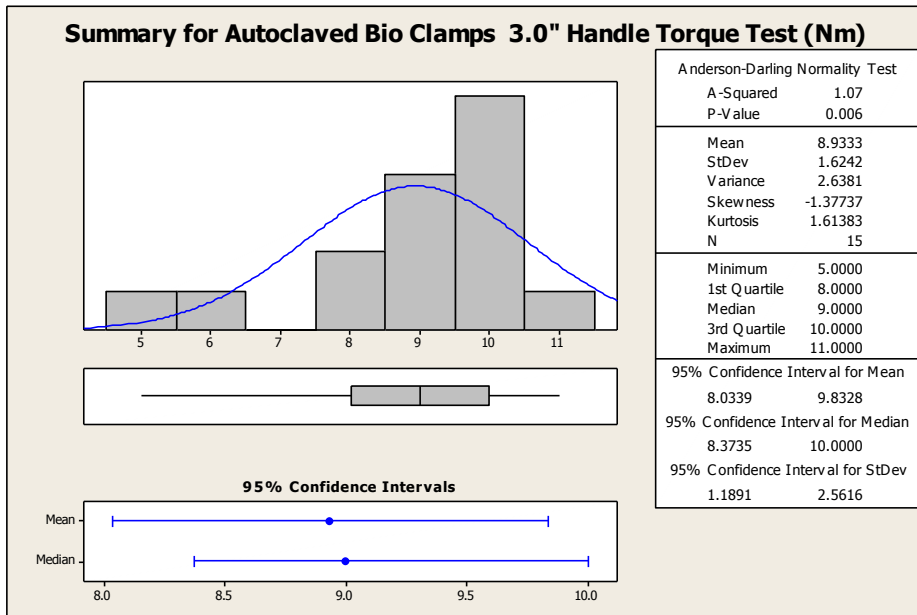


Figure 8.3.14 – Summary of Results for 3.0" Autoclaved Bio Clamp

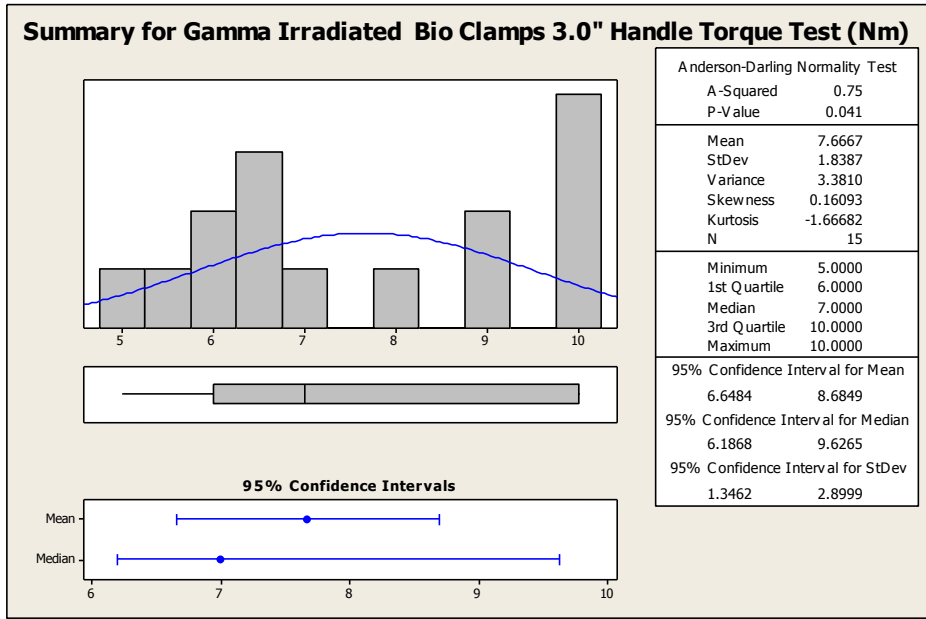


Figure 8.3.15 – Summary of Results for 3.0" Gamma Irradiated Bio Clamp

4.0" Bio Clamps

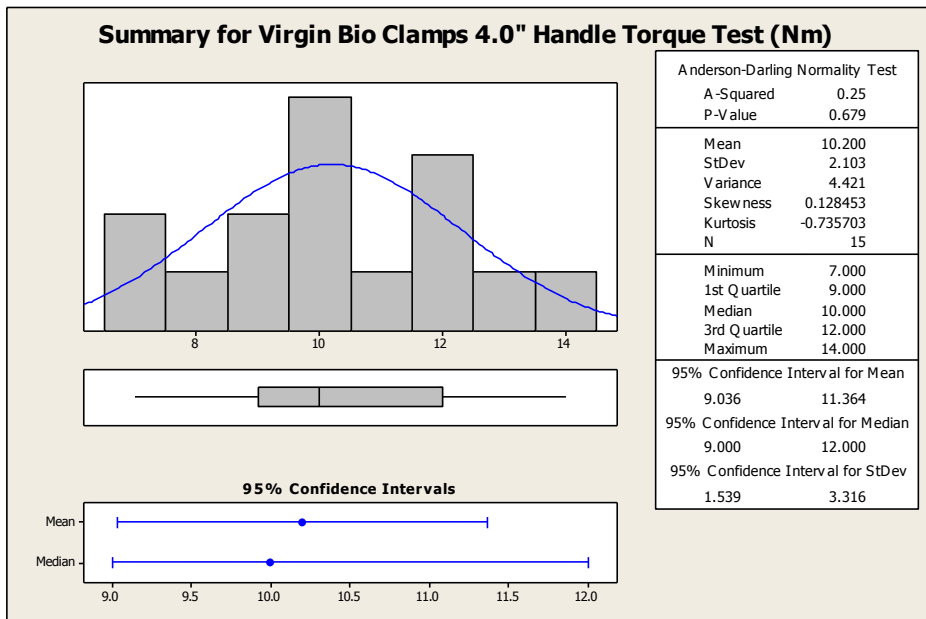


Figure 8.3.16 – Summary of Results for 4.0" Virgin Bio Clamp

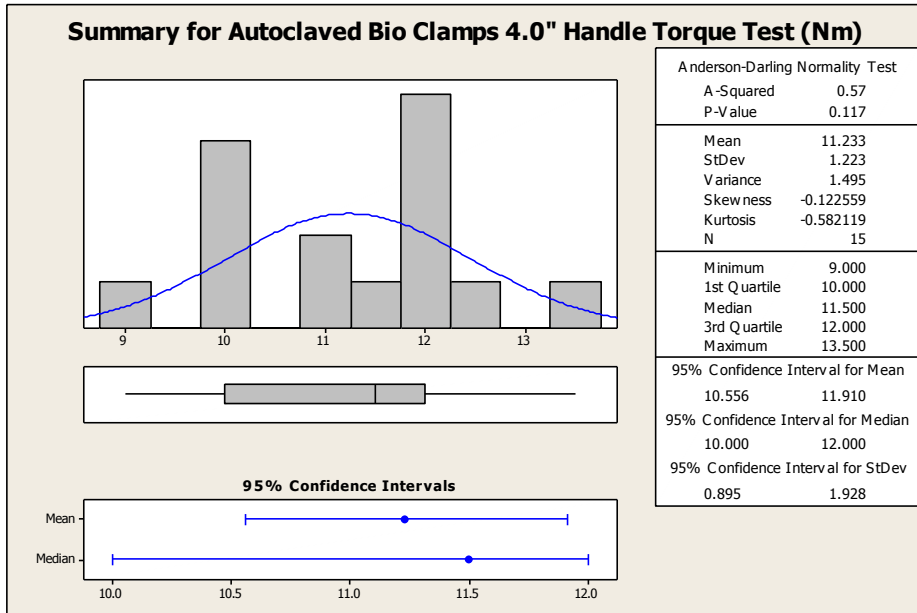


Figure 8.3.17 – Summary of Results for 4.0" Autoclaved Bio Clamp

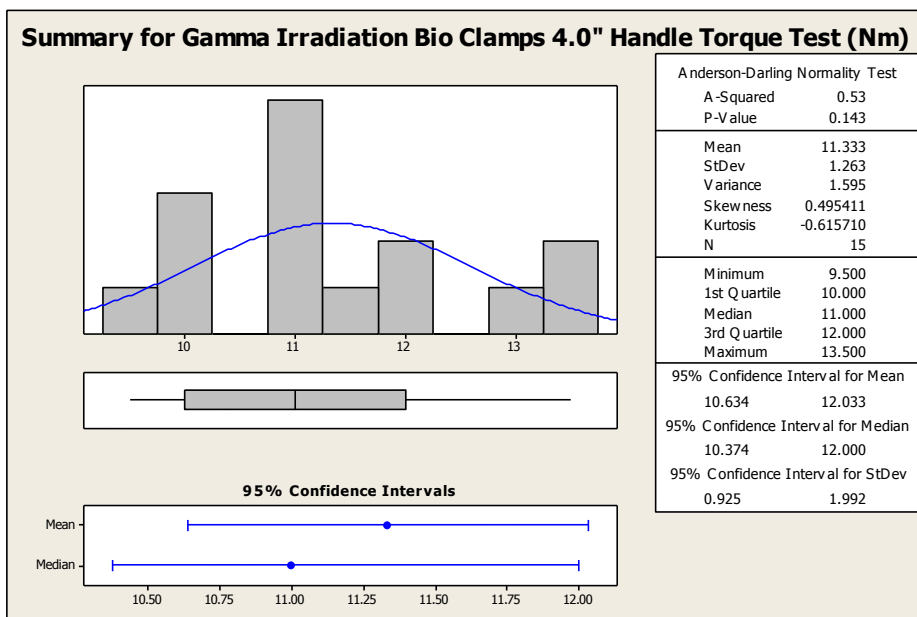


Figure 8.3.18 – Summary of Results for 4.0" Gamma Irradiated Bio Clamp

Test 3 – Additional 4.0” Clamp 100% Destructive Handle Torque Test

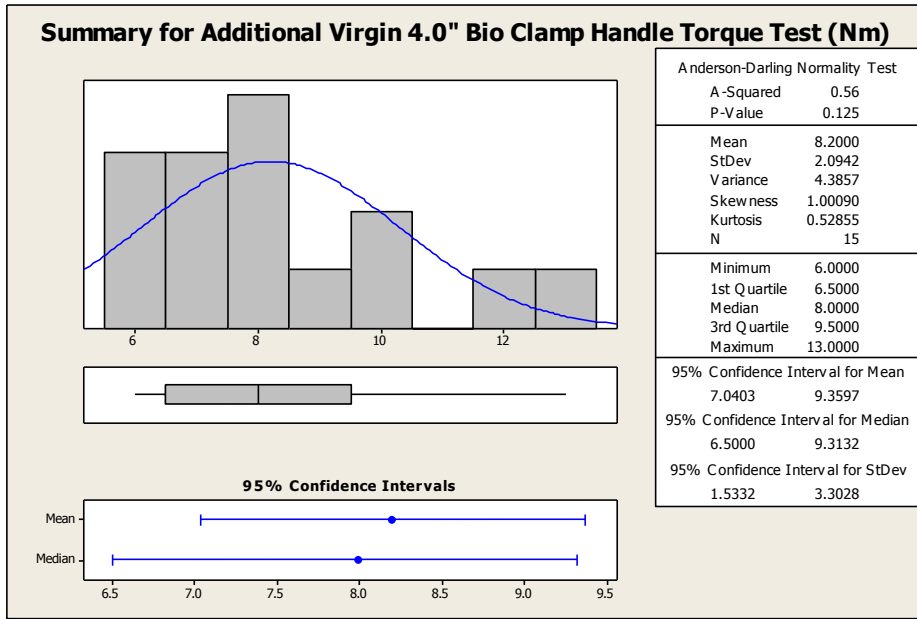


Figure 8.3.19 – Summary of Results for Additional 4.0” Virgin Bio Clamps

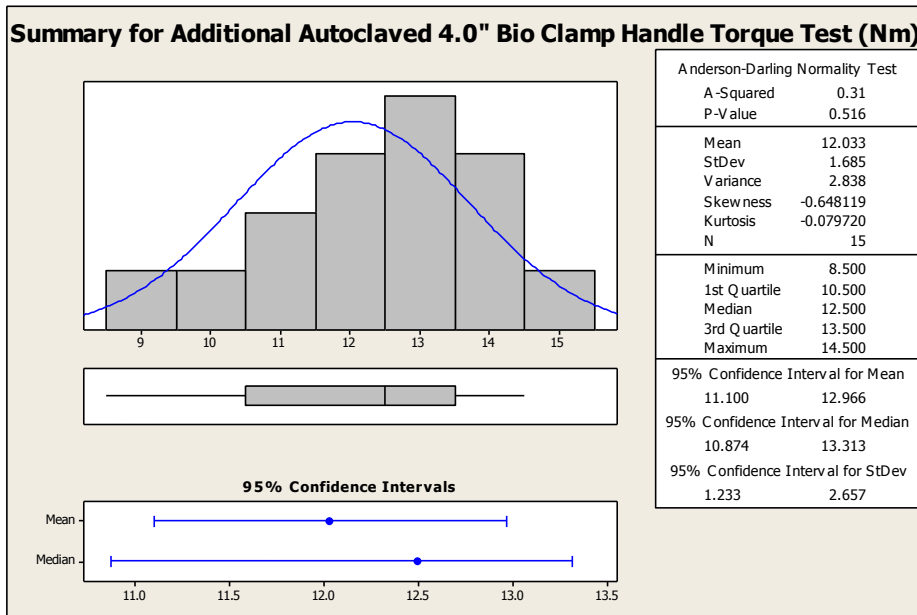


Figure 8.3.20 – Summary of Results for Additional 4.0” Autoclaved Bio Clamps

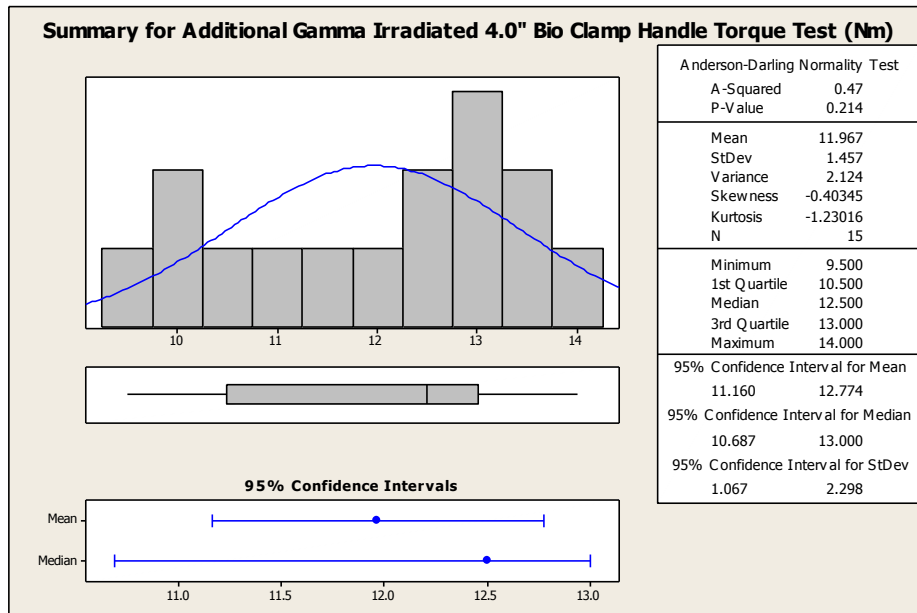


Figure 8.3.21 – Summary of Results for Additional 4.0” Gamma Irradiated

Summary of Results for Test 3

Clamp Type	Clamp Size	Mean Average Force at Failure (Nm)
Virgin Clamp	0.75"	7.200
Virgin Clamp	1.5"	8.633
Virgin Clamp	2.0"	7.266
Virgin Clamp	2.5"	9.466
Virgin Clamp	3.0"	8.833
Virgin Clamp	4.0"	10.200
Additional Virgin Clamp	4.0"	8.200
Autoclaved Clamp	0.75"	7.667
	1.5"	8.166
Autoclaved Clamp		
Autoclaved Clamp	2.0"	8.133
Autoclaved Clamp	2.5"	8.233
Autoclaved Clamp	3.0"	8.933
Autoclaved Clamp	4.0"	11.233
Additional Autoclaved Clamp	4.0"	12.033
Gamma Irradiated Clamp	0.75"	7.500
Gamma Irradiated Clamp	1.5"	8.300
Gamma Irradiated Clamp	2.0"	7.466
Gamma Irradiated Clamp	2.5"	7.933
Gamma Irradiated Clamp	3.0"	7.667
Gamma Irradiated Clamp	4.0"	11.333
Additional Gamma Irradiated Clamp	4.0"	11.966

Table 8.3.19 – Summary of Average Forces (Nm) at Failure for Test 3

8.4 Test 4 – Steam & Pressure Test. Clamps at 121°C

Clamp Type	Clamp Size	Average Pressure Drop over 30 Seconds (Bar)
Virgin Clamp	1.5"	0.008
Autoclaved Clamp	1.5"	0.01
Gamma Irradiated Clamp	1.5"	0.006

Table 8.4.1 – Results From Test 4

9. Schedule & Personnel

Ben Harris (Project Engineer) – Pressure testing, Steam & Pressure Testing of 1.5" Clamps, Heat & Pressure Testing and Handle Torque Testing

Dave Mitchell (Engineering Technician) – Pressure testing, Steam & Pressure Testing of 1.5" Clamps, Heat & Pressure Testing and Handle Torque Testing

10. Material Disposition

All the Bio Clamps used in the Tests will committed to land fill if agreed by Bio Pure Technology Ltd.