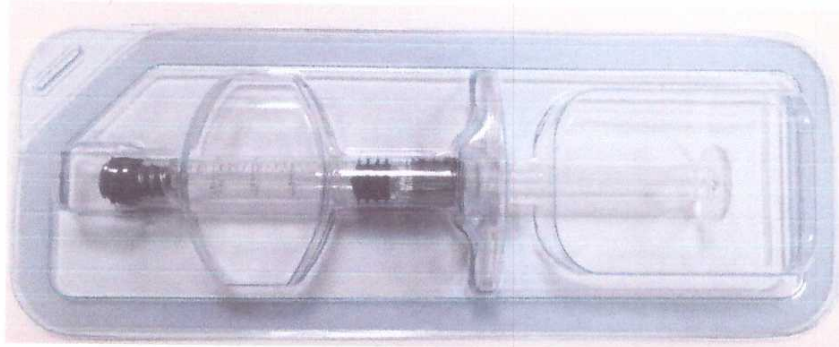


3YEARS SHELF LIFE TESTING REPORT

product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEb-JC
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Product Photo



manufacturer	Company	BioPlus.,LTD.
	County	Republic of Korea
Laboratory	Address	#211, Migun-Techno-World2, 187, Techno 2-ro, Yuseong-gu, Deajeon, Korea
	Company	BioPlus.,LTD. Labortory
Laboratory	Address	#211, Migun-Techno-World2, 187, Techno 2-ro, Yuseong-gu, Deajeon, Korea

Test Criteria	①	ASTM F 1980 Standard guide for Accelerated Aging of sterile medical device packages
	②	ASTM F 88 Test method for seal strength of flexible barrier materials
	③	ASTM F 1929 Test method for detecting seal leaks (Dye penetration)
	④	Stability test criteria of medical devices.
	⑤	The Korean Pharmacopoeia Tenth Edition - Sterility test, Actual Volume test of Injections

Test Date	Start date	2016. 6. 18	Tester	Sterility Test	Jeon, Eung-Jae
	End date	2016. 10. 6		Performance Test	Jeon, Eung-Jae

Writer	Name	Jeon, Eung-Jae	Reviewers Approver	Name	Park, Seongyung
	Signature			Signature	

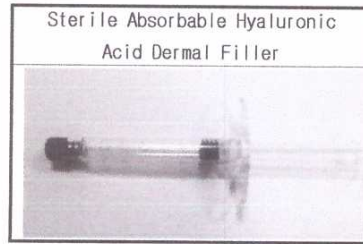
This report summarizes the results of 3 years shelf life testing of Graft/Prosthesis, Biomaterial of BioPlus.,LTD. Through this test, it is confirmed that the product is sterile and the performance is maintained for the duration of three year shelf life.

2016. 10. 6
 BioPlus Co., Ltd

I. Summary & Conclusion

1. General Information

- Manufacturer : Bioplus Co.,Ltd.
- Product Name : Sterile Absorbable Hyaluronic Acid Dermal Filler
- Test Location : Bioplus Co.,Ltd. Laboratory



2. Summary of results

Test Item	Standard	Unit	Criteria	Test results (3Lot average)			Conclusion
				Initial test	Middle test	Final test	
STRENGTH TESTING							
1. Adhesive Strength Test	ASTM F88	N	> 5.0N/25.4mm	Suitable	Suitable	Suitable	Pass
INTEGRITY TESTING							
1. Dye Penetration Test	A S T M F1929	-	No leakage	No leak	No leak	No leak	Pass
2. Sterility Test	ISO11737-2	-	Negative	Negative	Negative	Negative	Pass
PERFORMANCE TESTING							
1. Appearance Test	The content must be clear, transparent and viscous gel with no foreign object to the naked eye. Packaging should be free from scratches, twisting, pinhole.			Suitable	Suitable	Suitable	Pass
2. pH Test	When testing undiluted solution in accordance with pH measurement method in the Korean Pharmacopoeia test, pH should be 5.5 ~ 8.5.			Suitable	Suitable	Suitable	Pass
3. Actual Volume Test	When tested in accordance with actual volume test method of injection in the Korean Pharmacopoeia, it should be more than 3g. (But., 1g is 1ml.)			Suitable	Suitable	Suitable	Pass
4. Injection Force Test	Assemble the 27G, 13mm Normal wall needle(the bore 0.21mm) to 1cc syringe(the bore 6.35±0.1mm) filled with injection solution. when measuring the maximum value(N) of injecting at 12mm/min, the injection force should be 80~130N.			Suitable	Suitable	Suitable	Pass

3. Conclusion

Conclusion	Established shelf-life
1) To calculate the real-time shelf-life equivalent to 36 months of the product's 3 year shelf life, the ASTM F1980-02 Medical Device Stability Test Standard guideline was followed. By applying an accelerated aging temperature of 60 ± 2 °C(Q10=2.0), the result was 97 days of accelerated aging time equivalent to the real-time shelf-life of 36 months.	3 years
2) Physical test and sterility test were selected according to the standard criteria and product test by considering the specimen and manufacturing process of the evaluation criteria for the accelerated aging test. There were no difference in test results between before and after the accelerated aging. Therefore the shelf-life was concluded to be 3 years.	

II. QUALITY MANAGEMENT SYSTEM

1) Documentation

① The documentation of the SHELF LIFE TESTING REPORT was performed according to document and records management procedures[HTK-P-01].

② The review and approval of the SHELF LIFE TESTING were approved as follows.

Classification	Writer	Reviewer	Approver
Shelf life testing report	Jeon, Eungjae / Quality Manager	Park,Seongyung / Director	Park,Seongyung / Director
Testing report	Jeon, Eungjae / Quality Manager	Park,Seongyung / Director	Park,Seongyung / Director

2) Record

① All records in shelf life testing are performed according to document and records management procedures and they are stored permanently.

3) Design and development of the shelf-life protocol

① Design and development of the shelf-life protocol is performed according to design management procedure

4) Qualification and training

① The qualification of the shelf life testing is performed according to this report 7 (responsibility and authority)

② The training for the qualification is performed according to Human Resource Management Procedure[HTK-P-04].

5) Purchase

① Every resource used for shelf life testing such as the raw materials and equipment is performed according to the purchase procedure [HTK-12-P].

6) Identification and traceability

① Product and raw materials used for shelf life testing are performed according to the identification and traceability procedures [HTK-P-16].

7) Product verification

① The verification of products and raw materials is performed according to the monitoring and measurement procedures [HTK-P-19].

8) Calibration

① Measuring equipment used for shelf life testing is calibrated according to the monitoring and measurement equipment management procedures [HTK-P-18].

9) Nonconformity product control

① Nonconformity and nonconforming product occurred during shelf life testing are processed according to nonconforming product management procedures [HTK-P-21].

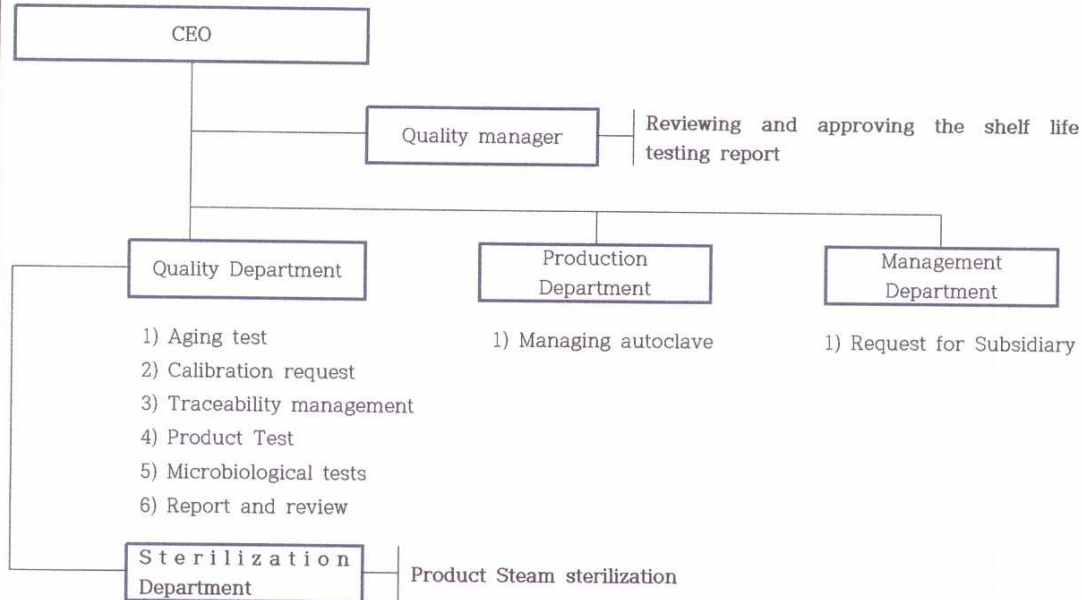
10) Corrective and preventive action

① Corrective and preventive action for the nonconformity is performed according to corrective and preventive action procedures [HTK-P-23].

III. RESPONSIBILITY AND AUTHORITY

1) Organizational structure and personnel

① Organizational structure and affairs



[별첨01] KGMP Certificate

② Personnel

No.	Name	Department	Field	Suitability
1	Park,Seongyoung	-	Medical Device	Report approved 적 합
2	Jeon, eungjae	QA	Medical Device	Report reviewed Products and microbiological tests 적 합

③ Qualification requirement

No.	Qualification	qualification requirements	Training Time
1	writer and reviewer of report	1) 2) 3) 4) 5) 6) training Completed	4 hours
2	Aging Tester	1) 2) 3) 4) 5) 6) training Completed	24 hours

(1) ASTM F1980:2002 Standard Guide for Accelerated Aging of Sterile Medical Device Package

(2) ASTM F88 Standard Test Method for Seal Strength of Flexible Barrier Materials

(3) ASTM F1929:2004 Standard Test Method for Detecting Seal Leaks (Dye Penetration)

(4) ISO11737-2:2006 Sterilization of medical devices – Microbiological methods Part 2:







Sterility tests

(5) Medical device suitability test standards









(6) Korean Pharmacopoeia_Sterility test and Actual Volume Test of injection

VI. EQUIPMENT TO BE USED AND CALIBRATION

1) Aging and testing equipment

Accelerated aging equipment		Appearance	thermograph		Appearance
Manufacturer	SciLab Korea		Manufacturer	LUTRON	
Product name	Oven		Product name	Thermo-hygrometer	
Model	SOF-W155		Model	HT-3007SD	
Standard	155L		Standard	Temperature range : -100~1300℃	
pH meter		Appearance	Scale for actual volume		Appearance
Manufacturer	EUTECH		Manufacturer	CAS	
Product name	pH Meter		Product name	Electric scales	
Model	Ph510		Model	CUW220H	
Standard	measurement 0~14 resolution 0.01		Standard	MAX 220g unit 0.001g	
Injection force		Appearance	magnifying glass		Appearance
Manufacturer	MARK-10		Manufacturer	Se-gi Optical	
Product name	Push-pull gauge		Product name	magnifying glass	
Model	M7-100		Model	-	
Standard	MAX 500N		Standard	Lens 5" 3x	

2) Testing equipment for Sterility and packaging testing

Clean benches and glassware	Autoclave	Test Media	Test strains
			
Incubator for bacteria	Incubator for fungi	Reagent for dye penetration test	Syringe for dye penetration test
			

[Attached02] Equipment calibration and Media certification

V. PRODUCT DESCRIPTION

1) Product Information

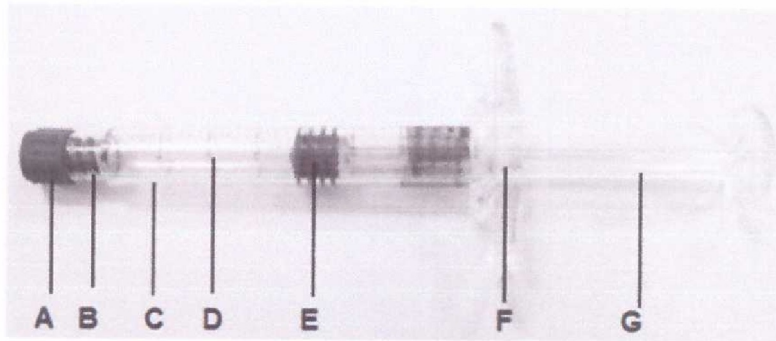
① Product name : Sterile Absorbable Hyaluronic Acid Dermal Filler

② Model name

SkinPlus-HYAL 100JC, HYALDEW-JC, DENEW-JC, BPLN-100JC, BPLN-60JC, BPL20-60JC, BPL30-60JC, BPLN-30JC, BPL20-27JC, BPL30-27JC, BPBN-31JC, BPLN-27JC

③ Figure and structure

① Sterile Absorbable Hyaluronic Acid Dermal Filler

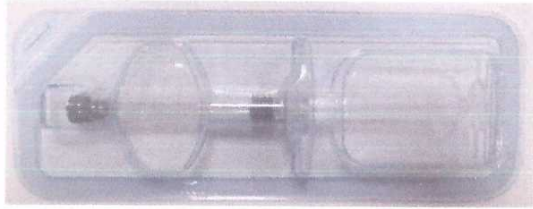
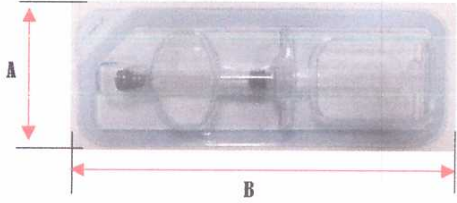


구분	명 칭	외 관 설 명
A	Tip Cap	Stopper to prevent leakage of product inserted in container (Luer-Lock Type)
B	Luer-Lock	Luer-Lock adapter to stably install injection needle
C	Container	Container and injector to make the product inserted and to enable injection into human body (Luer-Lock Type)
D	Injection Solution	Composed of crosslinked hyaluronic acid and phosphate buffer mixture
E	Stopper	Part to adjust injected amount
F	Grip	Handle used upon injecting the product
G	Plunger Rod	Part on which force is applied upon injecting the product

VI. PACKAGING/STERILIZATION SPECIFICATION AND METHOD

1) Packaging method and materials

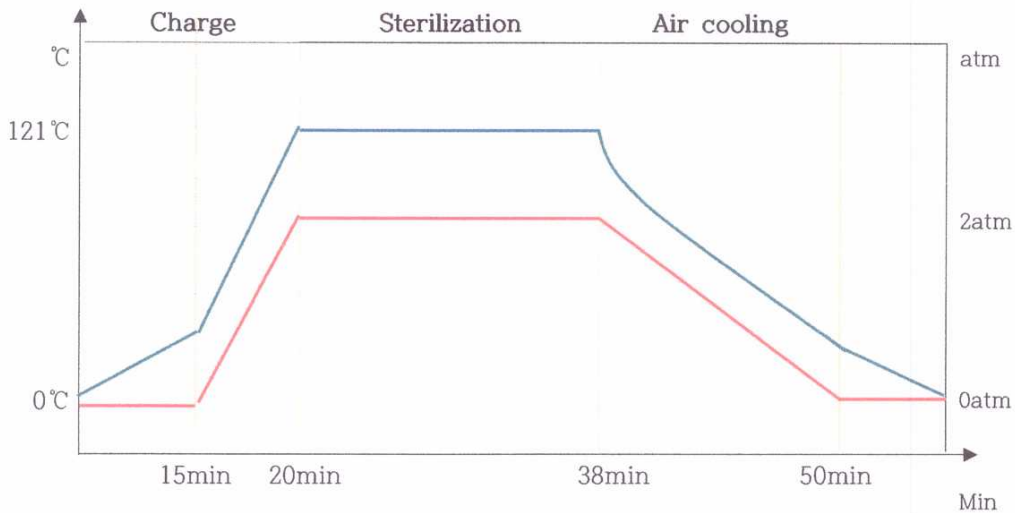
- After filling Graft/Prosthesis, Biomaterial to a glass syringe and sterilizing it, put the product in blister and package it with thermocompression bonding.

Packaging figure and materials		Packaging specification	
			
Syringe	COC	A	75mm
Film	PET Film	B	198mm
Paper	Tyvek paper	Packaging unit	
		1set / pack	

[Attached 03] MSDS for packaging material

2) Sterilization method and process parameter

- ① Composition of sterilizing agent -Purified water (steam sterilization)
- ② Sterilization assurance level : 10^{-6}
- ③ Cycle flow of steam sterilization



④ Steam sterilization process parameter

Item	Contents	Item	Contents
Sterilization method	High-pressure steam sterilization (ISO 17665-1)	Sterilization duration	18min.
Sterilization agent	Purified water	Temperature	121 °C

VII. ACCELERATED AGING CONDITIONS AND SAMPLING

1) ACCELERATED AGING TIME CONDITIONS

$$\text{Accelerated aging time} = \text{Real time} / Q_{10}^{[(\text{Accelerated temperature}-\text{Room temperature})/10]}$$

2) ACCELERATED AGING TIME

$$\text{Accelerated aging time} = \text{Real time} / Q_{10}^{[(\text{Accelerated temperature}-\text{Room temperature})/10]}$$

$$\text{Accelerated aging time} = 1095\text{days} / 2^{[(60-25)/10]}$$

$$\text{Accelerated aging time} = 1095\text{days} / 2^{3.5} = 1095\text{days} / 11.31 = 97 \text{ days}$$

Q10=2 (ASTM F1980 7.3.1 , 'Using the Arrhenius equation with Q10 equal to 2 is a common and means of calculating an aging factor')

Room or Ambient temperature : 25°C

Accelerated aging temperature : 60±2°C

Real time : 1095 days (3years)

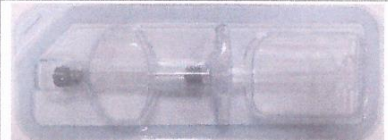
3) Accelerated aging start and finished date

구 분	날 짜	실제 가속 노화 기간
start date of accelerated aging	2016. 6. 16	97 days
end date of accelerated aging	2016. 9 . 21	

[별첨04] Aging temperature check-list

4) Sampling

① Product to be used on the shelf-life test

제 품 형 상	제 품 명	모 델 명
	Sterile Absorbable Hyaluronic Acid Dermal Filler	DENEBC-JC

② 투입수량 : Input Quantity : Produced model DENEBC-JC and empty wrapping paper for each LOT as below..

Sample	Model Name	Lot No	Manufactured date	Sterilization date	Q'ty
Lot No. #1	DENEBC-JC	FDBIM3CXX160401	2016. 4. 12	2016. 4. 12	45
	wrapping paper + empty syringe				30
	wrapping paper				30
Lot No. #2	DENEBC-JC	FDBIM3CXX160501	2016. 5. 3	2016. 5. 3	45
	wrapping paper + empty syringe				30
	wrapping paper				30
Lot No. #3	DENEBC-JC	FDBIM3CXX160502	2016. 5. 27	2016. 5. 27	45
	wrapping paper + empty syringe				30
	wrapping paper				30

VIII. AGING TESTING PROCEDURE

1) Separate samples in accordance with clause 7 by 1 LOT and put them in accelerated aging chamber except the first test quantity.



2) Set the temperature of the accelerated aging chamber to 60°C and time to Continuous.


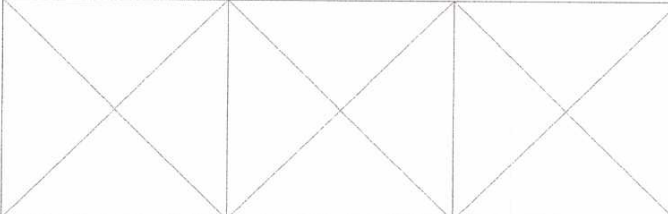
3) According to accelerated aging condition of clause 7, perform the related test in accordance with the following day after the accelerated aging.



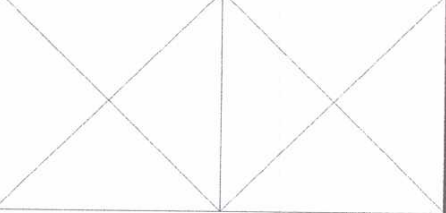
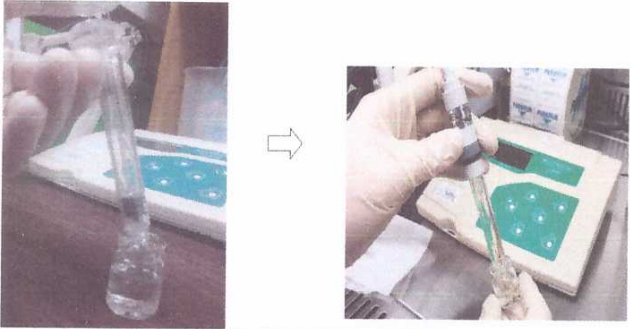
구분	1차 시험일	2차 시험일	3차 시험일
Lot #1	2016. 06. 18 (before accelerated aging)	2016. 7. 19 (after accelerated aging)	2016. 9. 21 (after accelerated aging)
Lot #2	2016. 06. 18 (before accelerated aging)	2016. 7. 19 (after accelerated aging)	2016. 9. 21 (after accelerated aging)
Lot #3	2016. 06. 18 (before accelerated aging)	2016. 7. 19 (after accelerated aging)	2016. 9. 21 (after accelerated aging)





4) Each item test quantity is as follows.

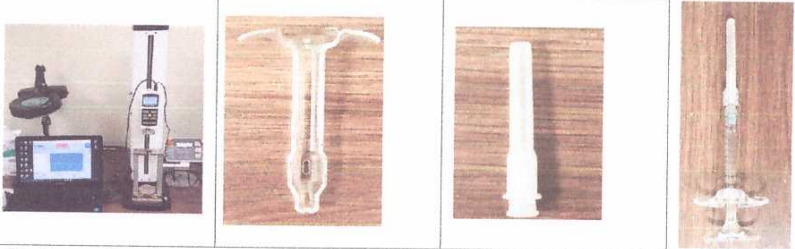
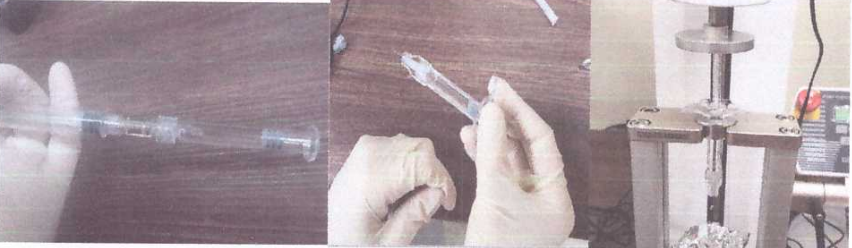
Test Item	Standard	Unit	Criteria	Requirement Quantity			Remarks
				Early	middle	Last	
STRENGTH TESTING							
1. Adhesive Strength Test	ASTM F88	N	> 5.0N	3	3	3	Empty wrapping paper
INTEGRITY TESTING							
1. Dye penetration Test	ASTM F1929	-	No leakage	3	3	3	Empty wrapping paper
2. Sterility Test	대한약전	-	Negative	3	3	3	Empty wrapping paper/Syringe
2. Sterility Test	대한약전	-	Negative	6	6	6	Product
PERFORMANCE TESTING							
1. Appearance Test	The content must be clear, transparent and viscous gel with no foreign object to the naked eye. Packaging should be free from scratches, twisting, pinhole.						
2. pH Test	When testing undiluted solution in accordance with pH measurement method in the Korean Pharmacopoeia test, pH should be 5.5 ~ 8.5.			3	3	3	Product
3. Actual Volume Test	When tested in accordance with actual volume test method of injection in the Korean Pharmacopoeia, it should be more than 3g. (But., 1g is 1ml.)						
4. Injection Force Test	Assemble the 27G, 13mm Normal wall needle(the bore 0.21mm) to 1cc syringe(the bore 6.35±0.1mm) filled with injection solution. when measuring the maximum value(N) of injecting at 12mm/min, the injection force should be 80~130N.			3	3	3	Product



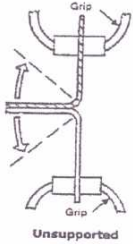
IX. TESTING PROCEDURE AND RESULTS



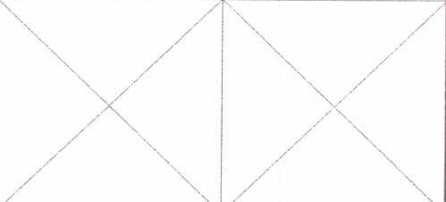

No.	Classification	Description									
1. Test Item : Appearance test											
①	Sampling Method	ISO2859-1 Once sampling S-1 general inspection) AQL 4.0									
②	Sample Q'ty	n=3 (Ac=0, Re=1)									
③	Test Equipment										
④	Test Method	☉ Appearance test is performed with the naked eye or magnifying glass.									
⑤	Test Criteria	☉ Appearance test The content must be clear, transparent and viscous gel with no foreign object to the naked eye. Packaging should be free from scratches, twisting, pinhole.									
⑥	Test Result	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)		
			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3
		Sample 01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
		Sample 02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Sample 03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
⑦	Judgment	Suitable									
⑧	Attached	[[Attached 05] Performance inspection reports									





No.	Classification	Description									
2. Test Item : pH test											
①	Sampling Method	ISO2859-1 Once sampling S-1 (general inspection) AQL 4.0									
②	Sample Q'ty	n=3 (Ac=0, Re=1)									
③	Test Equipment										
④	Test Method	<p>◎ Inject the solution of the product in the glass. ◎ Turn on the pH meter and measure pH.</p> 									
⑤	Test Criteria	◎ When testing undiluted solution in accordance with pH measurement method in the Korean Pharmacopoeia test, pH should be 5.5 ~ 8.5.									
⑥	Test Result	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)		
			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3
		Sample 01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
		Sample 02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Sample 03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
⑦	Judgment	Suitable									
⑧	Attached	[Attached 05] Performance inspection reports									

No.	Classification	Description									
3. Test Item : Actual Volume Test											
①	Sampling Method	ISO2859-1 Once sampling S-1 (general inspection) AQL 4.0									
②	Sample Q'ty	n=3 (Ac=0, Re=1)									
③	Test Equipment	 		X			X				
④	Test Method	<p>◎ Turn on the Precision balances, put the glass on it and adjust the zero point</p> <p>◎ Inject the solution of the product in the glass and inspect the volume.</p> <div style="display: flex; justify-content: space-around; align-items: center;">  ⇒  </div>									
⑤	Test Criteria	◎ When tested in accordance with actual volume test method of injection in the Korean Pharmacopoeia, it should be more than 3g. (But., 1g is 1ml.)									
⑥	Test Result	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)		
			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3
		Sample 01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
		Sample 02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Sample 03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
⑦	Judgment	Suitable									
⑧	Attached	[Attached 05] Performance inspection reports									

No.	Classification	Description									
4. Test Item : Injection Force Test											
①	Sampling Method	ISO2859-1 Once sampling S-1 general inspection) AQL 4.0									
②	Sample Q'ty	n=3 (Ac=0, Re=1)									
③	Test Equipment										
④	Test Method	<p>◎ Assemble the adaptor to 1cc syringe(the bore $6.35\pm 0.1\text{mm}$) and inject the solution of the product.</p> <p>◎ Assemble the 27G, 13mm Normal Wall (the bore 0.21mm) needle to 1cc syringe.</p> <p>◎ Assemble 1cc syringe to syringe holder and fix it to injection force tester.</p> <p>◎ Set the speed of injection force tester to 12mm/min and start.</p> 									
⑤	Test Criteria	◎ Assemble the 27G, 13mm Normal wall needle(the bore 0.21mm) to 1cc syringe(the bore $6.35\pm 0.1\text{mm}$) filled with injection solution. when measuring the maximum value(N) of injecting at 12mm/min, the injection force should be 80~130N.									
⑥	Test Result	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)		
			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3
		Sample 01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
		Sample 02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Sample 03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
⑦	Judgment	Suitable									
⑧	Attached	[Attached 05] Performance inspection reports									

No.	Classification	Description										
5. Test Item : Adhesive strength Test												
①	Sampling Method	ISO2859-1 (Once sampling S-1 general inspection) AQL 4.0										
②	Sample Q'ty	n=3 (Ac=0, Re=1)										
③	Test Equipment			X			X			X		
④	Test Method	<p>◎ Prepare the sample for packaging sealing test.</p> <p>◎ Cut each part of Coated paper and Film for each 25.4mm(width) X 10mm(height) and make the sample.</p> <p>◎ The moving speed of the tensile strength machine is 300mm/min. When the adhesive surface of the specimen is separated, calculate the maximum load.</p> <div style="display: flex; justify-content: space-around; align-items: center;">   </div>										
⑤	Test Criteria	◎ When tested with the above test method, each adhesive strength should be more than 5.0N/25.4mm.										
⑥	Test Result	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)			
			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	
		Sample 01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
		Sample 02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	
		Sample 03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
⑦	Judgment	Suitable										
⑧	Attached	[Attached 05] Performance inspection reports										

No.	Classification	Description									
6. Test Item : Dye Penetration Test											
①	Sampling Method	ISO2859-1 Once sampling S-1 general inspection) AQL 4.0									
②	Sample Q'ty	n=3 (Ac=0, Re=1)									
③	Test Equipment										
④	Test Method	<p>◎ Prepare the samples for dye penetration test.</p> <p>◎ Prepare dye penetrant solution made with Triton x 100 (0.5%), Toluidine blue (0.05%).</p> <p>◎ Using syringe, inject dye penetrant solution in the empty wrapping paper. Empty syringes are tested by sucking the dye solution penetration.</p> <p>◎ After leaning the wrapping paper to sterile coated paper and the part sealed with heat and filling 5mm height, observe above for each 30sec., and 1min. And fix the top and bottom of the empty syringe, observe it for one minute and test it.</p>									
											
⑤	Test Criteria	◎ When tested with the above test method and observed for 30 seconds and 1 minute in each section, the dyes should not leak.									
⑥	Test Result	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)		
			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3
		Sample 01	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
		Sample 02	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Sample 03	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass		
⑦	Judgment	Suitable									
⑧	Attached	[Attached 05] Performance inspection reports									

No.	Classification	Description																																																	
7. Test Item : Sterility test																																																			
①	Sampling Method	ISO2859-1 Once sampling S-1 general inspection) AQL 4.0																																																	
②	Sample Q'ty	n=3 (Ac=0, Re=1)																																																	
③	Test Equipment	   																																																	
④	Test Method	<p>◎ Growth promotion test Test containers of each medium were inoculated with not more than 100 CFU viable microorganisms of each listed in Table as below or other strains considered to be equivalent to these strains. Those were incubated at the temperature specified for the sterility test. Each of the test organisms should show apparent growth for not more than 3 days in the case of bacteria and not more than 5 days in the case of fungi.</p> <p>◎ Method suitability test for bacteriostasis and fungistasis a. the specified portion of the article and contain only the test media (positive control) were inoculated with not more than 100 CFU viable microorganisms of the standard strains or other equivalent strains. b. The fluid thioglycollate medium was incubated at (30 ~ 35) °C and soybean-casein digest medium at (20 ~ 25) °C to observe growth of the microorganisms for not more than 5 days. If the growth of any test organism is not observed in the test tubes and the growth (or growth rate) is less than the positive controls, it will be considered that the product possesses antimicrobial activity. In this case, a suitable neutralizing agent which does not affect the antimicrobial activity or increasing the volume of medium will be used.</p> <p>◎ Sterility test (Direct transfer method) 1. The test sample was inoculated into each of fluid thioglycollate medium and soybean-casein digest medium. The fluid thioglycollate medium was incubated at (30 ~ 35) °C and soybean-casein digest medium at (20 ~ 25) °C for not less than 14 days. The test vessels for growth of microorganisms were observed at least once between the fifth and ninth day, two times in total. If the sample makes the medium turbid so that the determination of presence or absence of microbial growth is difficult or in other case of need, suitable portions of the medium can be transferred into fresh vessels of the same medium and incubated at the same temperature for more than four days.</p> <p>2. Judgement If microbial growth is found, the product tested fails to meet the requirement of the test for sterility. The sterility test itself is inadequate and the test is repeated. The result indicate that the test article has sterility suitability under the no evidence of microbial growth was found.</p>																																																	
⑤	Test Criteria	◎ When tested in accordance with test method, it should be negative.																																																	
⑥	Test Result	<table border="1"> <thead> <tr> <th rowspan="2">Classification</th> <th colspan="3">1st test(before aging)</th> <th colspan="3">2nd test(after aging)</th> <th colspan="3">3rd test(after aging)</th> </tr> <tr> <th>Lot#1</th> <th>Lot#2</th> <th>Lot#3</th> <th>Lot#1</th> <th>Lot#2</th> <th>Lot#3</th> <th>Lot#1</th> <th>Lot#2</th> <th>Lot#3</th> </tr> </thead> <tbody> <tr> <td>Sample 01</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> </tr> <tr> <td>Sample 02</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> </tr> <tr> <td>Sample 03</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> <td>negative</td> </tr> </tbody> </table>	Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)			Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Sample 01	negative	negative	negative	negative	negative	negative	negative	negative	negative	Sample 02	negative	negative	negative	negative	negative	negative	negative	negative	negative	Sample 03	negative	negative	negative	negative	negative	negative	negative	negative	negative
Classification	1st test(before aging)			2nd test(after aging)			3rd test(after aging)																																												
	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3	Lot#1	Lot#2	Lot#3																																										
Sample 01	negative	negative	negative	negative	negative	negative	negative	negative	negative																																										
Sample 02	negative	negative	negative	negative	negative	negative	negative	negative	negative																																										
Sample 03	negative	negative	negative	negative	negative	negative	negative	negative	negative																																										
⑦	Judgment	Suitable																																																	
⑧	Attached	[Attach06] Sterility Test Report																																																	

CERTIFICATE

SZUTEST TEKNİK KONTROL VE BELGELENDİRME HİZM. TİC. LTD. ŞTİ.

Hereby declares on the basis of the positive results of the certification audit that the medical-devices quality management system implemented by;

BioPlus Co., Ltd.

#211, Migun Techno World 2, 187 Techno 2-ro, Yuseong-gu, Daejeon 34025, Korea

Was found to be in compliance with the requirements of

EN ISO 13485:2012
ISO 13485:2003

The present certificate is valid for the following products and processes

Design, Development, Manufacturing & Sales of
Sterile Absorbable Hyaluronic Acid Dermal Filler

Registration No : 31411902
Issue Date : 2014.04.29
Expiration Date : 2017.04.28
Revision Date / No : 2016.03.18 / 01

This certificate is valid if company meets the certification requirements of SZUTEST.




General Manager
Mehmet Işıklar

This version of certificate has come into force on 2013.11.06

교정성적서

CALIBRATION CERTIFICATE

(주)나노하이테크 대전광역시 유성구 배울1로 271 Tel) 042-671-2380, Fax)861-0512 e-mail : nanoht@nanoht.co.kr	성적서번호 (Certificate No.): 16-12911 페이지 (1) / (총 2) Page of Pages	
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1. 의뢰자 (Client)

기관명 (Name) : 바이오플러스㈜
 주소 (Address) : 대전광역시 유성구 테크노2로 187, 미건테크노월드 2차 211호

2. 측정기 (Calibration Subject)

기기명 (Description) : 고분자 박막 습도계(온습도계)
 제작회사 및 형식 (Manufacturer & Model Name) : Lutron / HT-3007SD
 기기번호 (Serial Number) : Q584865 (BD-M-001)

3. 교정일자 (Date of Calibration) : 2016. 05. 25

4. 교정환경 (Environment)

온도(Temperature) : (24.9 ± 1.1) °C 습도(Humidity) : (39.0 ± 1.4) % R.H.
 교정장소(Location) 교정표준실(Calibration Lab.) 이동교정 (Mobile Lab.) 현장교정(On Site Cal)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and / or brief description)



상기 기기는 박막형온습도계 교정지침서(NANO-I-0524)에 따라 국가측정표준기관으로부터 측정의 소급성이 확보된 아래의 장비를 이용하여 비교교정 되었다.

교정에 사용한 표준장비 명세 (List of used standards / specifications)

기기명 (Description)	제작회사 및 형식 (Manufacturer and Model)	기기번호 (Serial Number)	차기교정예정일자 (The due date of next calibration)	교정기관 (Calibration Lab)
DEWPOINT METER	EDGETECH / DEWMASTER	37399	2016. 10. 13	SICT
CHAMBER	VOTCH / VC34018	58566142300010	2016. 10. 02	NANO Hi-Tech
IPRT	JMS / 12-17-09	37399	2016. 06. 03	NANO Hi-Tech
DC bridge	ASL / F600 DC	011326/10	2016. 11. 13	SICT

6. 교정결과 (Calibration results): " 교정결과 참조"

7. 측정불확도 (Measurement uncertainty) : "교정결과 참조"

확인 (Affirmation)	작성자 (Measurements performed by) 성명 (Name): 홍아현 	승인자 (Approved by) 직위 (Title): 기술책임자 (Technical Manager) 성명 (Name): 강수석 
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위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

2016. 06. 01

한국인정기구 인정
 Accredited by KOLAS, Republic of KOREA

(주) 나노하이테크 대표이사
 Nano Hitech Co., Ltd.



이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다. 이 성적서의 진위확인은 왼쪽 상단의 전화 또는 이메일로 연락주시면 확인하실 수 있습니다.

교정결과

CALIBRATION RESULTS

성적서번호: 16-12911
Certificate No.

페이지(2) / (총 2)
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- * 기기명 (Description) : 고분자 박막 습도계(온습도계)
- * 제작회사 및 형식 (Manufacturer & Model Name) : Lutron / HT-3007SD
- * 기기번호 (Serial Number) : Q584865 (BD-M-001)

◎ 상대습도 측정 DATA 20 ℃ 에서

기준기지사값	기기지사값	보정값	측정불확도 신뢰수준 약 95 %, k=2
30.0 % R.H.	32.5 % R.H.	-2.5 % R.H.	
50.0 % R.H.	52.3 % R.H.	-2.3 % R.H.	2.7 % R.H.
75.0 % R.H.	73.3 % R.H.	1.7 % R.H.	


◎ 온도 측정 DATA

기준기지사값	기기지사값	보정값	측정불확도 신뢰수준 약 95 %, k=2
10.0 ℃	10.0 ℃	0.0 ℃	
20.0 ℃	20.0 ℃	0.0 ℃	0.4 ℃
30.0 ℃	30.1 ℃	-0.1 ℃	

끝.

교정성적서

CALIBRATION CERTIFICATE

㈜나노하이테크 대전광역시 유성구 배울1로 271 Tel) 042-671-2380, Fax)861-0512 e-mail : nanoht@nanoht.co.kr	성적서번호(Certificate No.): 16 - 12910 페이지(1) / (총 2) Page of Pages	
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1. 의뢰자 (Client)

기관명 (Name) : 바이오플러스㈜
 주소 (Address): 대전광역시 유성구 테크노2로 187, 미전테크노월드 2차 211호

2. 측정기 (Calibration Subject)

기기명 (Description) : 디지털온도계
 제작회사 및 형식 (Manufacturer & Model Name) : Lutron / HT-3007SD
 기기번호 (Serial Number) : Q584865

3. 교정일자 (Date of Calibration) : 2016. 05. 26

4. 교정환경 (Environment)

온도(Temperature): (25.4 ± 0.6) °C 습도(Humidity): (47.7 ± 1.4) % R.H.
 교정장소(Location): 교정표준실(Calibration Lab.) 이동교정 (Mobile Lab.) 현장교정(On Site Cal)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and / or brief description)

상기 기기는 온도지시/기록/제어장치 교정지침서(NANO-I-0503)에 따라 국가측정표준기관으로부터 측정의 소급성이 확보된 아래의 장비를 이용하여 비교교정 되었다.

교정에 사용한 표준장비 명세 (List of used standards / specifications)

기기명 (Description)	제작회사 및 형식 (Manufacturer and Model)	기기번호 (Serial Number)	차기교정예정일자 (The due date of next calibration)	교정기관 (Calibration Lab)
IPRT Thermometer	ASL / T100-450	N0412A-1.3	2017. 04. 27	NANO Hi-Tech
Bath	ASL / F201	016224/16	2016. 07. 23	SICT
	FLUKE / 6331	B04313	2016. 08. 27	NANO Hi-Tech

6. 교정결과 (Calibration results): " 교정결과 참조"

7. 측정불확도 (Measurement uncertainty) : "교정결과 참조"

확인 (Affirmation)	작성자 (Measurements performed by) 성명 (Name): 홍아현	승인자 (Approved by) 직위 (Title): 기술책임자 (Technical Manager) 성명 (Name): 강수석
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위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

2016. 06. 01

한국인정기구 인정
 Accredited by KOLAS, Republic of KOREA

㈜ 나노하이테크 대표이사
Nano Hitech Co., Ltd.



※ 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다. 이 성적서의 진위확인용 왼쪽 상단의 전화 또는 이메일로 연락주시면 확인하실 수 있습니다.

교정결과

CALIBRATION RESULTS

정적서번호: 16-12910
Certificate No.

페이지(2) / (총 2)
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* 기기 명 (Description) : 디지털온도계

* 제작회사 및 형식 (Manufacturer & Model Name) : Lutron / HT-3007SD

* 기기번호 (Serial Number) : Q584865

센서포함 TC

기준기치값 (Standard Value)	기기치값 (Indicated Value)	보정값 (Correction)	Measurement Uncertainty (C.L.:Approx. 95 %, $k=2$)
0.00 °C	0.0 °C	0.0 °C	0.3 °C
99.99 °C	99.7 °C	0.3 °C	0.3 °C
200.04 °C	200.5 °C	- 0.5 °C	0.3 °C
END.			

Correction = Standard - Indicated Value

시험 성적서

CERTIFICATE OF TEST

㈜나노하이테크 대전광역시 유성구 배울1로 271 Tel) 862-0220, Fax)861-0512 http://www.nanoht.co.kr	성적서번호(Certificate No.): 16-0520-01 페이지(1) / (총 2) Page of Pages	
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1. 의뢰자 (Client)
 기관명 (Name) : 바이오플러스㈜
 주소 (Address) : 대전광역시 유성구 테크노2로 187, 미건테크노월드2차 211호
2. 측정기 (Test Subject)
 시료명 (Description) : pH meter
 제작회사 (Manufacturer) : EUTECH
 형식 및 기기번호 (Model Name & Serial Number) : Ph510 / 565665
3. 시험일자 (Date of Test) : 2016. 05. 20
4. 시험환경 (Environment)
 온도(Temperature) : (24.5 ± 0.0) ℃ 상대습도 (Relative Humidity) : (43 ± 0) % R.H.
 시험장소(Location) : 고정표준실(NanoHi-Tech Lab.) 이동시험 (Mobile Lab.) 현장시험(On Site Test)
5. 시험방법 (Test method used)
 KS M 0011, KS A 5105

시험에 사용한 표준장비 명세 (List of used standards / specifications)

사용장비명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	인증기관 Calibration Laboratory
STANDARD BUFFER	OMEGA / pH 4.01	4AI515	OMEGA
STANDARD BUFFER	OMEGA / pH 7.00	4AI624	OMEGA
STANDARD BUFFER	OMEGA / pH 10.01	4AI735	OMEGA

6. 시험결과 (Testing results): " 시험결과 참조"

확인 (Affirmation)	시험자 (Tested by) 성명 (Name): 백중빈	승인자 (Approved by) 직위 (Title): 기술책임자 (Technical Manager) 성명 (Name): 백승일
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위 성적서는 ㈜나노하이테크에서 시행한 시험 성적임을 증명함

2016. 06. 07

㈜ 나노하이테크 대표이사


Nano Hitech Co., Ltd.



㈜ 이 성적서의 내용은 의뢰자가 제공한 시료의 시험 결과이며, 상업적인 광고나 또는 분쟁해결을 위하여 사용될 수 없습니다.

시험결과

TESTING RESULTS

㈜나노하이테크 대전광역시 유성구 배울1로 271 Tel) 862-0220, Fax)861-0512 http://www.nanoht.co.kr	성적서번호(Certificate No.): 16-0520-01 페이지(2) / (총 2) Page of Pages	
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1. 시험대상품목

- * 시 료 명 : pH meter
- * 제작회사 : EUTECH
- * 형 식 : Ph510
- * 기물번호 : 565665

2. 시험성적서의 용도

: 품질관리용


3. 시험결과

시험항목	기준값 (pH)	지시값 (pH)	비고
1) 재현성시험	4.01 pH	4.04 pH	pH 4 스펀교정후 측정값
	7.00 pH	6.99 pH	pH 7 스펀교정후 측정값
	10.01 pH	10.00 pH	pH 10 스펀교정후 측정값
* 측정시 해당구간 span calibration 후 사용해야 합니다.			

끝.

교정성적서

CALIBRATION CERTIFICATE

(주)나노하이테크 대전광역시 유성구 배울1로 271 Tel)042-671-2380, Fax)861-0512 e-mail : nanoht@nanoht.co.kr	성적서번호(Certificate No.) : 16-12843 페이지(1) / (총 2) Page of Pages	
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1. 의뢰자 (Client)

기관명 (Name) : 바이오플러스㈜
 주소 (Address) : 대전광역시 유성구 테크노2로 187, 미전테크노월드 2차 211호

2. 측정기 (Calibration Subject)

기기명 (Description) : 전기식지시저울 (Electric balance)
 제작회사 및 형식 (Manufacturer & Model Name) : CAS / CUW220H
 기기번호 (Serial Number) : D454000022

3. 교정일자 (Date of Calibration) : 2016. 05. 20

4. 교정환경 (Environment)

온도(Temperature) : (26.2 ± 0.1) °C 습도(Humidity) : (39.6 ± 0.3) % R.H.
 교정장소(Location) : 교정표준실(Calibration Lab.) 이동교정 (Mobile Lab.) 현장교정(On Site Cal)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and / or brief description)

상기 기기는 전기식지시저울 교정지침서(NANO-I-0402)에 따라 국가측정표준기관으로부터 측정의 소급성이 확보된 아래의 장비를 이용하여 비교교정 되었다.

교정에 사용한 표준장비 명세 (List of used standards / specifications)

기기명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	차기교정예정일자 The due date of next Calibration	교정기관 Calibration Lab
Standard weight	중앙정밀 F1급	6002	2016. 08. 02	Nano-Hitech

6. 교정결과 (Calibration results) : "교정결과 참조"

7. 측정불확도 (Measurement uncertainty) : "교정결과 참조"

확 인 (Affirmation)	작성자 (Measurements performed by) 성명 (Name): 조광한	승인자 (Approved by) 직위 (Title): 기술책임자 (Technical Manager) 성명 (Name): 백승일
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위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

2016. 06. 02

한국인정기구 인정
 Accredited by KOLAS, Republic of KOREA

(주) 나노하이테크 대표이사
 Nano Hitech Co., Ltd.



(주) 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다. 이 성적서의 진위확인에는 상담의 전화 또는 이메일로 연락주시면 확인하실 수 있습니다.

교정결과 CALIBRATION RESULT

대전광역시 유성구 배울1로 271
http://www.nanoht.co.kr

성적서번호(Certificate No.) : 16-12843

페이지(2) / (총 2)
Page of Pages



■ 기기명 (Description) : 전기식저서저울 (Electric balance)

- * 최대 용량 (Capacity): 220 g
- * 해독도 (Readability): 0.001 g
- * 표준 편차 (Standard deviation): 0.000 55 g
- * 편심 오차 (Eccentricity error): 0.001 g
- * 측정 불확도 (Measurement uncertainty) : 0.002 g
신뢰수준 (Confidence level) 약 95 %, k : 2

* 직 선 성 (Linearity)


표준분동의 상용질량값 (Mass value)	지 시 값 (Indication value)		보 정 값 (Correction value)	
	증가 (Increase)	감소 (Decrease)	증가 (Increase)	감소 (Decrease)
0.000	0.000	0.000	0.000	0.000
50.000	49.999	50.000	0.001	0.000
100.000	99.999	100.000	0.001	0.000
150.000	150.000	150.000	0.000	0.000
200.000	199.999	199.999	0.001	0.001

* 보 정 값 = 상용질량값 - 지 시 값
(correction = conventional mass value - indication value)

End.

교정성적서

CALIBRATION CERTIFICATE

㈜나노하이테크 대전시 유성구 배울1로 271 Tel) 042-671-2380, Fax)861-0512 e-mail : nanoht@nanoht.co.kr	성적서번호(Certificate No.): 16-20194 페이지(1) / (총 2) Page of Pages	
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1. 의뢰자 (Client)

기관명 (Name) : 바이오플러스㈜
 주소 (Address) : 대전광역시 유성구 테크노2로 187, 미건테크노빌드 2차 211호

2. 측정기 (Calibration Subject)

기기명 (Description) : 푸쉬풀 게이지 (Push-Pull gauge)/(Pull 방향)
 제작회사 및 형식 (Manufacturer & Model Name) : MARK-10 / M7-100
 기기번호 (Serial Number) : 3681195

3. 교정일자 (Date of Calibration) : 2016. 07. 23

4. 교정환경 (Environment)

온도(Temperature) : (19.6 ± 0.1) °C 습도(Humidity) : (49.9 ± 0.3) % R.H.
 교정장소(Location) : 교정표준실(Calibration Lab.) 이동교정 (Mobile Lab.) 현장교정(On Site Cal)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and / or brief description)



상기 기기는 푸쉬풀 게이지 교정지침서(NANO-I-0702)에 따라 국가측정표준기관으로부터 측정의 소급성이 확보된 아래의 장비를 이용하여 비교교정 되었다.

교정에 사용한 표준장비 명세 (List of used standards / specifications)

기기명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	차기교정예정일자 The due date of next Calibration	교정기관 Calibration Lab
Weight	NANOHI-TECH	74-7	2017. 11. 30	NANOHI-TECH

6. 교정결과 (Calibration results) : "교정결과 참조"

7. 측정불확도 (Measurement uncertainty) : "교정결과 참조"

확인 (Affirmation)	작성자 (Measurements performed by) 성명 (Name): 이현수 	승인자 (Approved by) 직위 (Title): 기술책임자 (Technical Manager) 성명 (Name): 백승일 
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위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

2016. 08. 03

한국인정기구 인정

Accredited by KOLAS, Republic of KOREA

㈜ 나노하이테크 대표이사

Nano Hitech Co., Ltd.



이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(파부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다. 이 성적서의 진위확인은 왼쪽 상단의 전화 또는 이메일로 연락주시면 확인하실 수 있습니다.

교정결과 CALIBRATION RESULT

대전광역시 유성구 배울1로 271
http://www.nanoht.co.kr

성적서번호(Certificate No.) : 16-20194

페이지(2) / (총 2)

Page of Pages



■ 기기명 (Description) : 푸쉬풀 게이지 (Push-Pull gauge)/(Pull 방향)


실하중(N)	기기지시값(N)				상대정확도 오차 (%)	상대확장불확도 (%)	신뢰수준 약 95 %, k =
	1차	2차	3차	평균값			
0.0	0.0	0.0	0.0	0.0	-	-	-
98.0	97.9	97.9	98.0	97.9	-0.08	0.13	2.52
196.0	195.8	195.9	196.0	195.9	-0.02	0.13	3.31
294.0	294.0	294.0	294.1	294.0	0.03	0.13	2.37
391.9	392.1	392.2	392.1	392.1	0.04	0.13	2
489.9	490.1	490.1	490.2	490.2	0.05	0.13	2

* 시험기의 분해능(Resolution) : 0.098 N

* NANO-I-0702 에 따라 상대확장불확도, 상대정확도오차를 계산하였다. 끝.

교정성적서

CALIBRATION CERTIFICATE

㈜나노하이테크 대전시 유성구 배울1로 271 Tel) 042-671-2380, Fax)861-0512 e-mail : nanoht@nanoht.co.kr	성적서번호(Certificate No.) : 16-22824 페이지(1) / (총 2) Page of Pages	
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1. 의뢰자 (Client)

기관명 (Name) : 바이오플러스㈜
 주소 (Address) : 대전광역시 유성구 테크노2로 187, 미건테크노월드 2차 211호

2. 측정기 (Calibration Subject)

기기명 (Description) : 푸쉬풀 게이지 (Push-Pull gauge)/(Push 방향)
 제작회사 및 형식 (Manufacturer & Model Name) : MARK-10 / M7-100
 기기번호 (Serial Number) : 3681195

3. 교정일자 (Date of Calibration) : 2016. 08. 22

4. 교정환경 (Environment)

온도(Temperature) : (20.3 ± 0.1) °C 습도(Humidity) : (50.6 ± 0.8) % R.H.
 교정장소(Location) : 교정표준실(Calibration Lab.) 이동교정 (Mobile Lab.) 현장교정(On Site Cal)

5. 측정표준의 소급성 (Traceability)

교정방법 및 소급성 서술 (Calibration method and / or brief description)

상기 기기는 푸쉬풀 게이지 교정지침서(NANO-I-0702)에 따라 국가측정표준기관으로부터 측정의 소급성이 확보된 아래의 장비를 이용하여 비교교정 되었다.

교정에 사용한 표준장비 명세 (List of used standards / specifications)

기기명 Description	제작회사 및 형식 Manufacturer and Model	기기번호 Serial Number	차기교정예정일자 The due date of next Calibration	교정기관 Calibration Lab
Weight	NANOHI-TECH	74-7	2017. 11. 30	NANOHI-TECH

6. 교정결과 (Calibration results) : "교정결과 참조"

7. 측정불확도 (Measurement uncertainty) : "교정결과 참조"

확 인 (Affirmation)	작성자 (Measurements performed by) 성명 (Name): 김병진	승인자 (Approved by) 직 위 (Title) : 기술책임자 (Technical Manager) 성명 (Name): 백승일
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위 성적서는 국제시험기관인정협력체(International Laboratory Accreditation Cooperation) 상호인정협정(Mutual Recognition Arrangement)에 서명한 한국인정기구(KOLAS)로부터 공인받은 분야의 교정결과입니다.

2016. 08. 25

한국인정기구 인정 **㈜ 나노하이테크 대표이사**
 Accredited by KOLAS, Republic of KOREA **Nano Hitech Co., Ltd.**



㈜ 이 성적서는 측정기의 정밀정확도에 영향을 미치는 요소(과부하, 온도, 습도 등)의 급격한 변화가 발생한 경우에는 무효가 됩니다. 이 성적서의 진위확인 은 왼쪽 상단의 전화 또는 이메일로 연락주시면 확인하실 수 있습니다.

교정결과 CALIBRATION RESULT

대전광역시 유성구 배울1로 271
http://www.nanoht.co.kr

성적서번호(Certificate No.) : 16-22824

페이지(2) / (총 2)

Page of Pages



■ 기기명 (Description) : 푸쉬풀 게이지 (Push-Pull gauge)/(Push 방향)

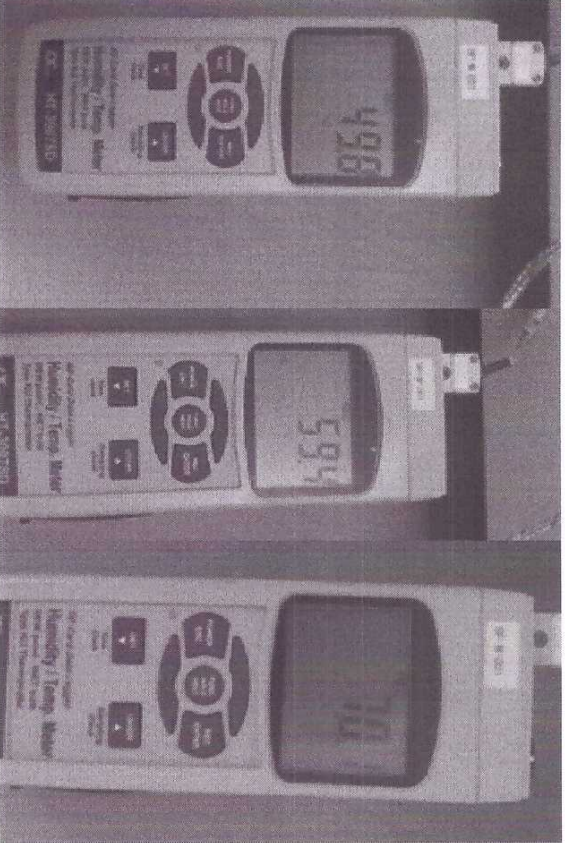
실하중(N)	기가지시값(N)				상대정확도 오차 (%)	상대확장불 확도 (%)	신뢰수준 약 95 %, k =
	1차	2차	3차	평균값			
0.0	0.0	0.0	0.0	0.0	-	-	-
98.0	98.1	98.2	98.1	98.1	0.15	0.13	2.52
196.0	196.2	196.3	196.3	196.3	0.15	0.13	2.43
294.0	294.4	294.5	294.4	294.4	0.16	0.13	2.37
391.9	392.5	392.6	392.6	392.6	0.16	0.13	2
489.9	490.7	490.8	490.8	490.8	0.17	0.13	2

* 시험기의 분해능(Resolution) : 0.1 N

* NANO-I-0702 에 따라 상대확장불확도, 상대정확도오차 를 계산하였다. 끝.

계측기 자가검정성적서

Calibration Certificate

관리 번호 No.			BP-E-030			계측기명 (Description)		국문	영문	오븐기 Oven	단위 ea / set
핵심규격 Specifications			155 L	S/N	0100236154Q001						
비교검정일자 Calibration Date			2016.05.30								
Date			Thermometers (Lutorn HT-3007SD , S/N: Q584865) Calibration Date: 2016.05.25 Calibration Lab :NANO Hi-Tech Next Calibration Date: 2017.05.24								
검정표준장비 List of used standards			검정환경 (Calibration Lab) : BioPlus Lab 검정방법 (Calibration Method) : And using standard equipment, measures the temperature of the 3 point.								
검정방법 및 검정환경 Calibration Method			#1			#2			#3		
RESULT (°C)			Standard equipment	49.8	59.4	70.1					
Calibration subject			50	60	70						
Result of calibration			After the correction action			Next Calibration Date 2017.05.29					
Error of less than 1 °C in the use environment			No compensation value			Affirmation Written by Approved by					
The installation place of the equipment: Lab			5 / 30			5 / 30					



Technical Safety Information Sheet

Chemical Product and Manufacturer

Product Name: M-8519
Product Description: Peelable Heat Seal Coated Tyvek® Pouch and Lidding
Date Prepared: November 6, 2009
Manufacturer: Alcan Packaging
Medical Flexibles - Americas
8770 West Bryn Mawr Ave.
Chicago, IL 60631
Comments: M-8519 Heat Seal Coated Tyvek® which we currently supply is considered an Article as defined by 29CFR 1910.1200
Other Information: OSHA Hazard Communication Standard 29CFR 1910.1200 requirements for Material Safety Data Sheets do not apply to this product. This product is excluded as an Article. Information on potential hazards associated with this product fabrication and or installation are discussed in this technical safety information.

Information on Ingredients

Name: CAS#: Mixture and Polyethylene
DOT Hazard Classification: Non-hazardous
DOT Shipping Name: Not regulated
DOT Label: None

Hazard Identification

Emergency Overview: This product has no known adverse effect on human health. Additives in this product do not present a respiration hazard unless the product is ground to a powder of repairable size and the dust is inhaled. All dusts are potentially injurious to the respiratory tract if repairable particles are generated and inhaled. Dust may form explosive mixture in air.

First Aid Measures

General Advice: No hazards which require special first aid measures

Fire Fighting Measures:

Fire and Explosion: Burning is accompanied by melting and dripping which may cause the fire to spread. Hazardous combustion products include carbon monoxide and carbon dioxide (CO₂) and other unknown by products
Flash Point: Not Applicable

Fire Fighting: Wear self-contained breathing apparatus and protective suit. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Handling and Storage:

Handling: Minimize the generation of dust
Storage: Do not expose to freezing
Rotate Inventory and refer to Alcan warranty for use by and storage conditions
Keep protected from UV light exposure and combustion exhaust fumes

Personal Protection:

Respiratory: Respiratory protection should not be required for normal use and handling. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Exposure Limits: AEL- Respirable Dust 8-12 hr. TWA 5mg/m3
AEL- Total Dust 8-12hr. TWA 10mg/m3

Chemical Properties:

Color: White
Odor: None

Transportation Information:

Information: Not classified as dangerous in the meaning of transportation regulations

Additional Information:

Restrictions For
Use:

Do not use materials in medical applications involving implantation in the human body or contact with internal body fluids or tissues
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated any may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.



Certificate of Analysis

Becton Dickinson and Company
 BD Diagnostic Systems
 PO Box 999
 Sparks MD 21152-0999 US

Product Name : Bottle Bacto TSB Casein Med 500G
Catalog Number : 211825 **Manufacture Date** : 2016/06/09
Batch Number : 6189527
Expiration Date : 2021/04/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
 02. Solubility: 3% solution, soluble in distilled or deionized water
 03. Solution Appearance: Light amber, clear
 04. Medium was tested per European (EP), Japan (JP), and United States Pharmacopeia (USP) Growth Promotion requirements. Tubes were inoculated with < 100 CFUs. Tubes were incubated aerobically for 3 days and up to 5 days for (*) organisms and gave cultural responses as indicated.

TEST ORGANISMS	ATCC®	RECOVERY	TEMPERATURE	INCUBATION
*Asperigillus brasiliensis	16404	growth	20-25°C	Up to 5 days
Bacillus subtilis	6633	growth	30-35°C, 20-25°C	Up to 3 days
*Candida albicans	10231	growth	20-25°C	Up to 5 days
Escherichia coli	8739	growth	30-35°C	Up to 3 days
Pseudomonas aeruginosa	9027	growth	30-35°C	Up to 3 days
Salmonella typhimurium	14028	growth	30-35°C	Up to 3 days
Staphylococcus aureus	6538	growth	30-35°C	Up to 3 days

05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at the temperatures specified for 18-48 hours, or up to 72 hours if necessary.

TEST ORGANISMS	ATCC®	TEMPERATURE	RECOVERY
Neisseria meningitidis	13090	30-35°C	fair to good
Staphylococcus epidermidis	12228	30-35°C	good
Streptococcus pneumoniae	6305	30-35°C	good
Streptococcus pyogenes	19615	30-35°C	good

06. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Tryptic Soy Broth indicates that there is less than 5000 ppm of Acetone. No other solvents were detected during analysis.

Characteristic	Unit	Value	Lower Limit	Upper Limit
Loss on Drying :	%	2	0	5
pH at 25°C :		7.3	7.1	7.5
Bulk Lot Number :	-	6153603		

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Bovine	New Zealand	IV	IV	MLK
Porcine	USA	III	III	IB



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Page: 2 of 3

Product Name	: Bottle Bacto TSB Casein Med 500G		
Catalog Number	: 211825	Manufacture Date	: 2016/06/09
Batch Number	: 6189527		
Expiration Date	: 2021/04/30		

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 9001:2008 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), are regulated by the FDA's Quality System Regulations (QSRs), and are also ISO 13485:2003 Registered. This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at <http://www.bd.com/regdocs>. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD. See "COA Animal Origin Information Position Statement" located at <http://www.bd.com/regdocs> under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", at <http://www.bd.com/regdocs> under "Position Statements".

Manufacturer is Becton Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA. To determine location of manufacturing for this product, please see www.bd.com/ds/technicalCenter/regulatory.asp.



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Page: 3 of 3

Product Name : Bottle Bacto TSB Casein Med 500G
Catalog Number : 211825 **Manufacture Date** : 2016/06/09
Batch Number : 6189527
Expiration Date : 2021/04/30

Charlotte Dannenfelser
BD Life Sciences - Diagnostic Systems
Quality Director, Microbiology
Signature Date: 2016/08/03



Certificate of Analysis

Becton Dickinson and Company
 BD Diagnostic Systems
 PO Box 999
 Sparks MD 21152-0999 US

Product Name : Bottle Fluid Thioglycollate Med 500G
Catalog Number : 225650 **Manufacture Date** : 2016/01/05
Batch Number : 6026596
Expiration Date : 2020/09/30

01. Dehydrated Medium Appearance: Light beige, free-flowing, homogeneous
02. Solubility: 2.98% solution, soluble in distilled or deionized water on boiling
03. Solution Appearance: Hot - light amber, clear. At room temperature - light amber, slightly opalescent, 10% or less of upper layer is medium pink. After shaking solution becomes pink throughout.
04. Mercurial neutralization test was carried out using 1% Merthiolate with Staphylococcus aureus ATCC® 6538P and Streptococcus pyogenes ATCC® 19615. Merthiolate was neutralized by this lot.
05. Cultural Response: Medium was prepared per label instructions. Tubes were inoculated with the test organisms and incubated at 30-35°C for 18-48 hours, or up to 76 hours if necessary.

TEST ORGANISMS	ATCC®	RECOVERY
Clostridium novyi	7659	good
Clostridium perfringens	13124	good
Staphylococcus aureus	25923	good
06. Medium was also tested per European (EP), Japanese (JP) and United States Pharmacopeia (USP) Growth Promotion requirements. Inoculum of < 100 CFUs was used and tubes were incubated for up to 3 days.

Pharmacopeia Growth Promotion:

Bacillus subtilis	6633	growth
Bacteroides vulgatus	8482	growth
Clostridium sporogenes	11437	growth
Clostridium sporogenes	19404	growth
Micrococcus luteus	9341	growth
Pseudomonas aeruginosa	9027	growth
Staphylococcus aureus	6538	growth
07. Residual Solvents (CPMP/ICH/283/95): Typical Analysis for Fluid Thioglycollate medium did not detect any solvents.

Characteristic	Unit	Value	Lower Limit	Upper Limit
Loss on Drying :	%	2.0	0.0	5.0
pH at 25°C :		7.3	6.9	7.3
Bulk Lot Number:	-	5348678		

Animal source	Country of Origin	Tissue Category		
		BIC	SIC	ABC
Avian	China	IV	IV	NDF



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Product Name	: Bottle Fluid Thioglycollate Med 500G
Catalog Number	: 225650
Batch Number	: 6026596
Expiration Date	: 2020/09/30
	Manufacture Date : 2016/01/05

Bovine	New Zealand	IV	IV	MLK
Porcine	USA	III	III	IB

For an avian origin ingredient used in the manufacture of this product, the BD supplier is not able to confirm animal health. The supplier has confirmed that the ingredient undergoes extensive processing that includes exposure to strong acid, filtration, crystallization, and drying.

The Batch Number on this certificate is synonymous with the Lot Number shown on the product label.

BD Diagnostics - Diagnostic Systems products are manufactured in ISO 9001:2008 Registered facilities. In addition, BD Diagnostics - Diagnostic Systems facilities are registered with the United States Food and Drug Administration (FDA), are regulated by the FDA's Quality System Regulations (QSRs), and are also ISO 13485:2003 Registered. This product met BDDS stringent quality standards at time of batch/lot release. Any test results reported on this certificate were obtained at time of release. This material is not for human or animal consumption.

BD Diagnostics - Diagnostic Systems' Certificates of Analysis (COA) typically contain animal origin information when products are manufactured using materials of animal origin. This information may be contained in the animal source table and/or in one or more of the additional paragraphs found on the COA. Following Quality Control release, the COA is created and published at <http://www.bd.com/regdocs>. For each batch of finished product that contains animal origin raw materials, the COA shows the animal origin data from the individual lots of animal origin raw materials used, as provided by the raw material suppliers.

At times, suppliers notify BD Diagnostics - Diagnostic Systems of new and/or additional information they have received from their raw material suppliers that modifies the animal origin information for lots previously provided to BD. See "COA Animal Origin Information Position Statement" located at <http://www.bd.com/regdocs> under "Position Statements" for the impact that retrospective information has on COAs and on customers enrolled in the BDDS and BDAB Automated Change Notification Program.

For complete details on animal origin information, refer to "BD Position Statement - BD Diagnostic-Diagnostic Systems, COA Animal Origin Information Position Statement", at <http://www.bd.com/regdocs> under "Position Statements".

Legal manufacturer (Division Headquarters) is Becton, Dickinson and Company, 7 Loveton Circle, Sparks, MD 21152 USA.



Certificate of Analysis

Becton Dickinson and Company
BD Diagnostic Systems
PO Box 999
Sparks MD 21152-0999 US

Page: 3 of 3

Product Name : Bottle Fluid Thioglycollate Med 500G
Catalog Number : 225650 **Manufacture Date** : 2016/01/05
Batch Number : 6026596
Expiration Date : 2020/09/30

Charlotte Dannenfelser
BD Life Sciences - Diagnostic Systems
Quality Director, Microbiology
Signature Date: 2016/02/05



PERFORMANCE TEST CERTIFICATE

Written by 	Reviewed by 	Approved by
06 / 18	/	06 / 18

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160401
Date of manufacture	2016. 04. 12	Tester	Jeong, Eungjae	Inspection Date	2016. 06. 18

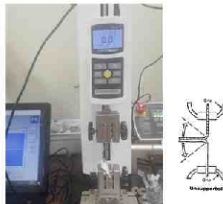



No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable		
		Packaging	Packaging should be free from scratches, twisting, pinhole.			Suitable	Suitable	Suitable		
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.83	6.81	6.83			
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.124	3.320	3.222			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	112.8	124.7	118.7			
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	6.4	6.8	7.6			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
					No Leak	No Leak	No Leak			
	No Leak	No Leak	No Leak							



PERFORMANCE TEST CERTIFICATE

Written by <i>[Signature]</i>	Reviewed by 	Approved by <i>[Signature]</i>
06 / 18	/	06 / 18

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160501
Date of manufacture	2016. 05. 03	Tester	Jeon, eungjae	Inspection Date	2016. 06. 18

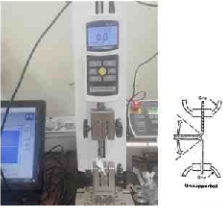



No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable	 	
		Packaging	Packaging should be free from scratches, twisting, pinhole.			Suitable	Suitable	Suitable		
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.83	6.82	6.83	 	 	
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.202	3.112	3.116			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	118.4	121.2	124.3	 	 	
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	8.5	6.1	7.4			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak. 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
					No Leak	No Leak	No Leak	 	 	
	No Leak	No Leak	No Leak	 	 					



PERFORMANCE TEST CERTIFICATE

Written by	Reviewed by	Approved by
06 / 18	/	06 / 18

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160502
Date of manufacture	2016.05.27	Tester	Jeong, Eungjae	Inspection Date	2016. 06. 18

No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable		
		Packaging				Packaging should be free from scratches, twisting, pinhole.	Suitable	Suitable	Suitable	
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.83	6.84	6.83			
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.123	3.220	3.218			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	117.9	116.2	125.6			
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	6.9	6.5	7.0			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak. 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
						No Leak	No Leak	No Leak		
						No Leak	No Leak	No Leak		

1st L1-1.log

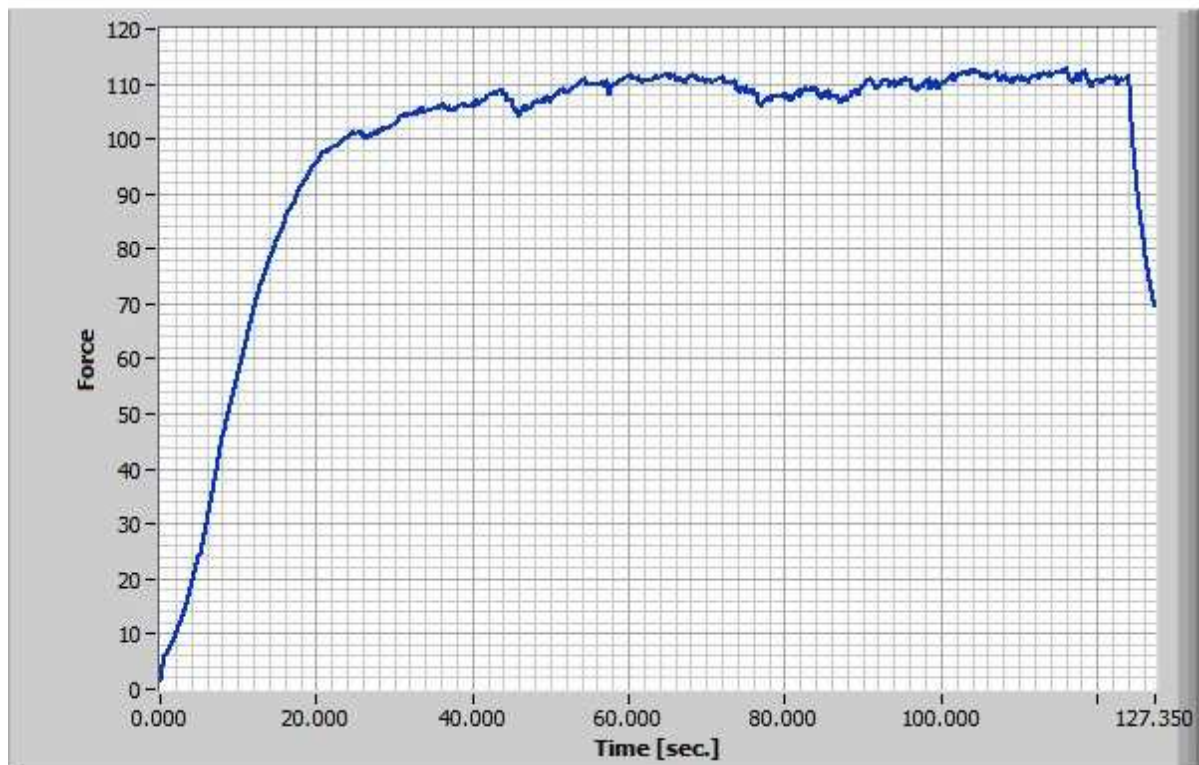
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 127.350

Statistics

Maximum: 112.8000
Minimum: 1.6000
Average: 99.2749
Area Under Curve: 12642.6612
Standard Deviation: 23.4163
Variance: 548.3254



1st L1-2.log

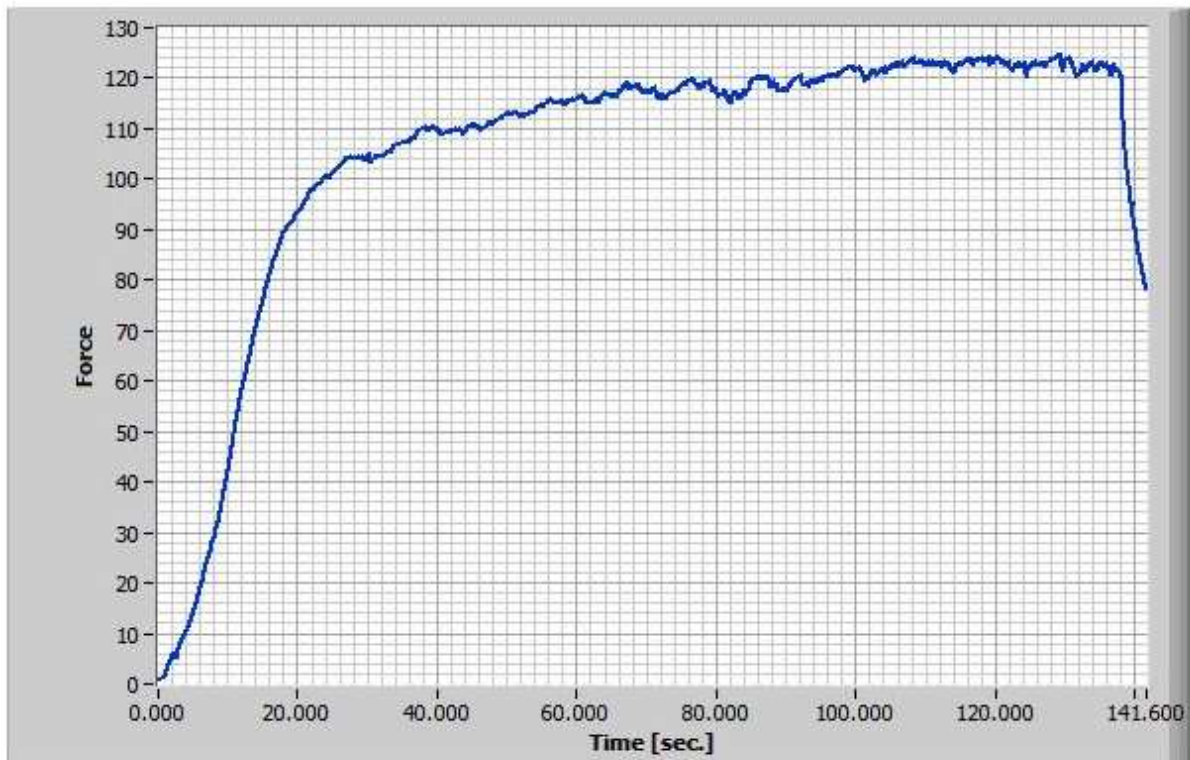
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 141.600

Statistics

Maximum: 124.7000
Minimum: 0.7000
Average: 105.6771
Area Under Curve: 14963.8789
Standard Deviation: 28.1907
Variance: 794.7152



1st L1-3.log

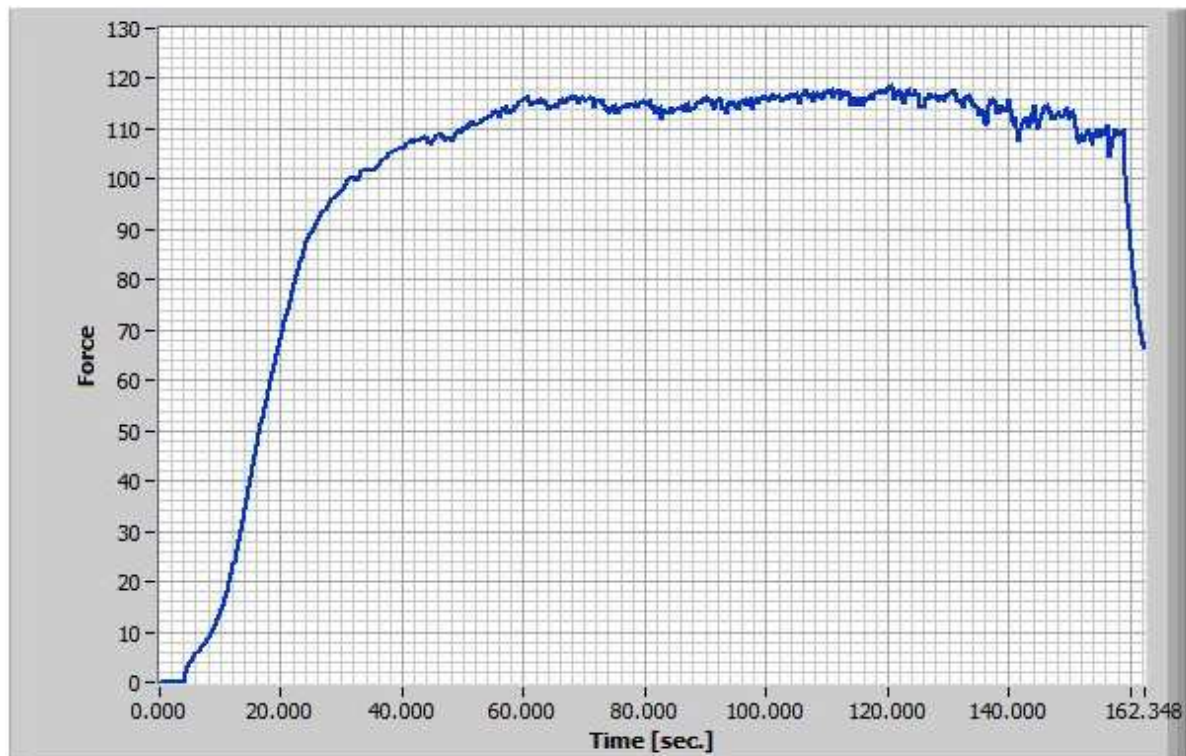
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 162.348

Statistics

Maximum: 118.7000
Minimum: 0.0000
Average: 99.6112
Area Under Curve: 16171.6713
Standard Deviation: 31.1611
Variance: 971.0154



1st L2-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 151.299

Statistics

Maximum: 118.4000

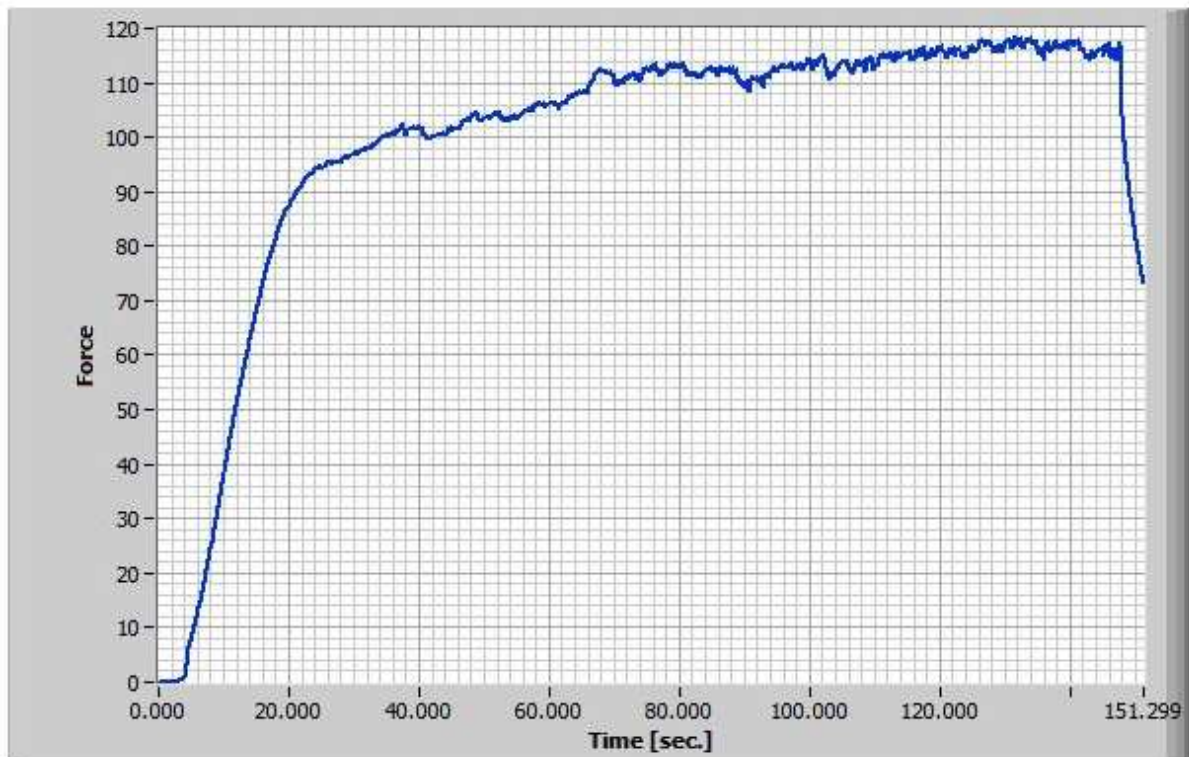
Minimum: 0.0000

Average: 99.4735

Area Under Curve: 15050.2405

Standard Deviation: 27.1760

Variance: 738.5356



1st L2-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 166.352

Statistics

Maximum: 121.2000

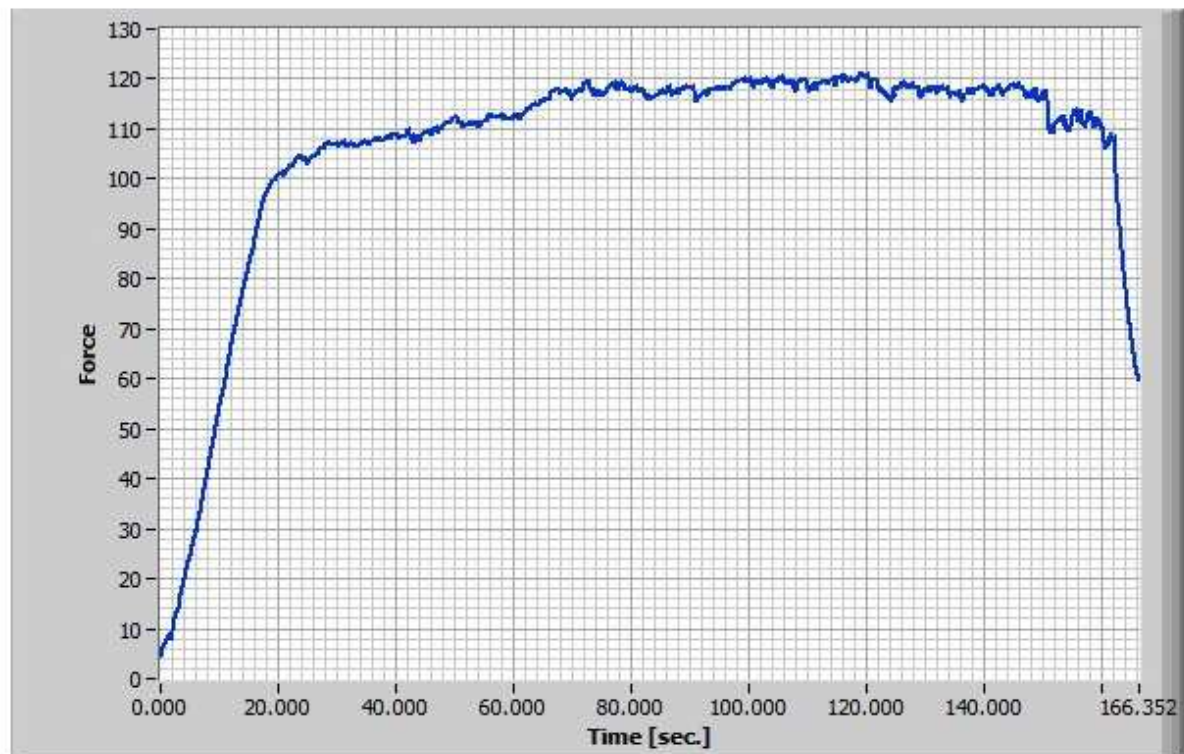
Minimum: 4.5000

Average: 106.4584

Area Under Curve: 17709.5658

Standard Deviation: 23.5594

Variance: 555.0462



1st L2-3.log

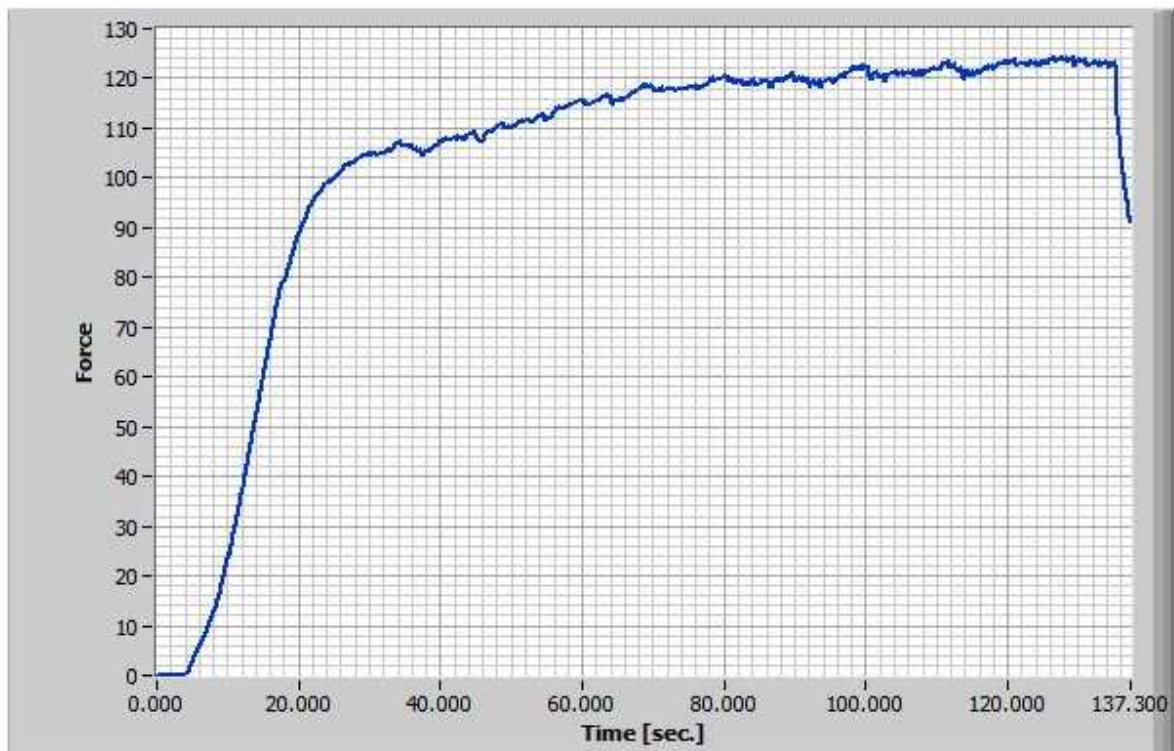
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 137.300

Statistics

Maximum: 124.3000
Minimum: 0.0000
Average: 103.2785
Area Under Curve: 14180.1425
Standard Deviation: 32.3190
Variance: 1044.5192



1st L3-1.log

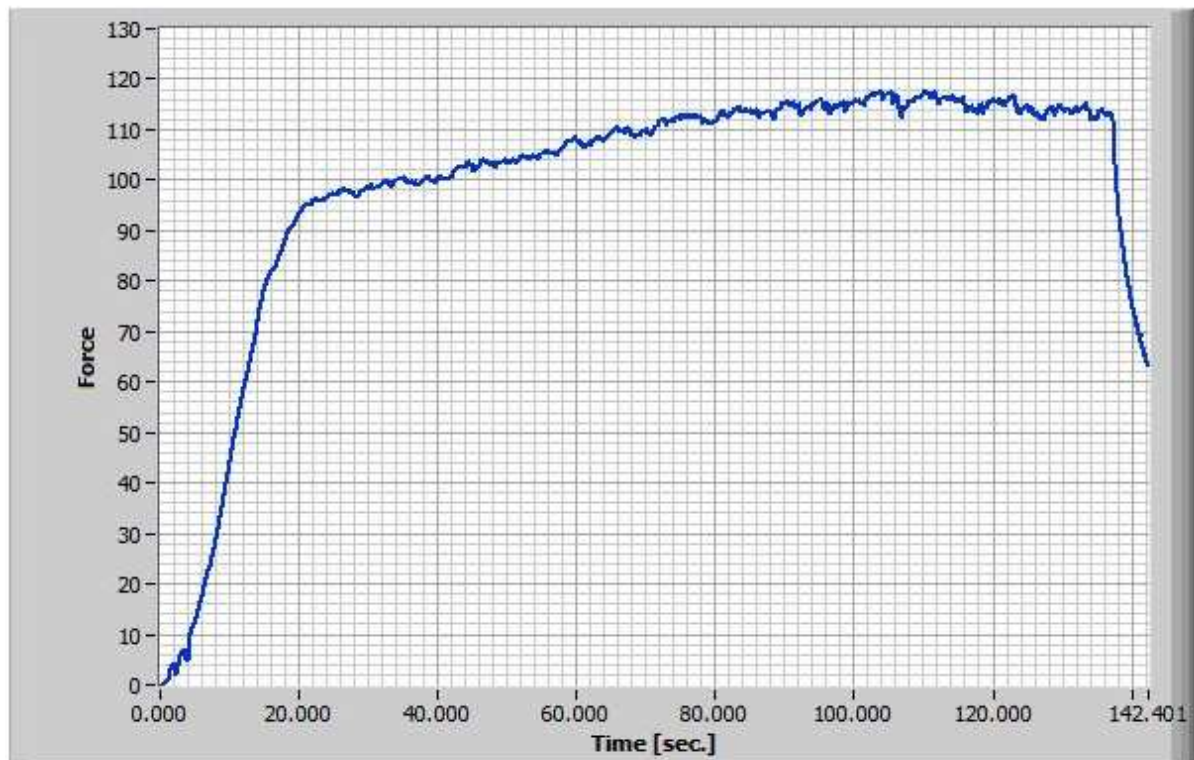
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 142.401

Statistics

Maximum: 117.9000
Minimum: 0.0000
Average: 99.1921
Area Under Curve: 14125.0484
Standard Deviation: 26.3738
Variance: 695.5790



1st L3-2.log

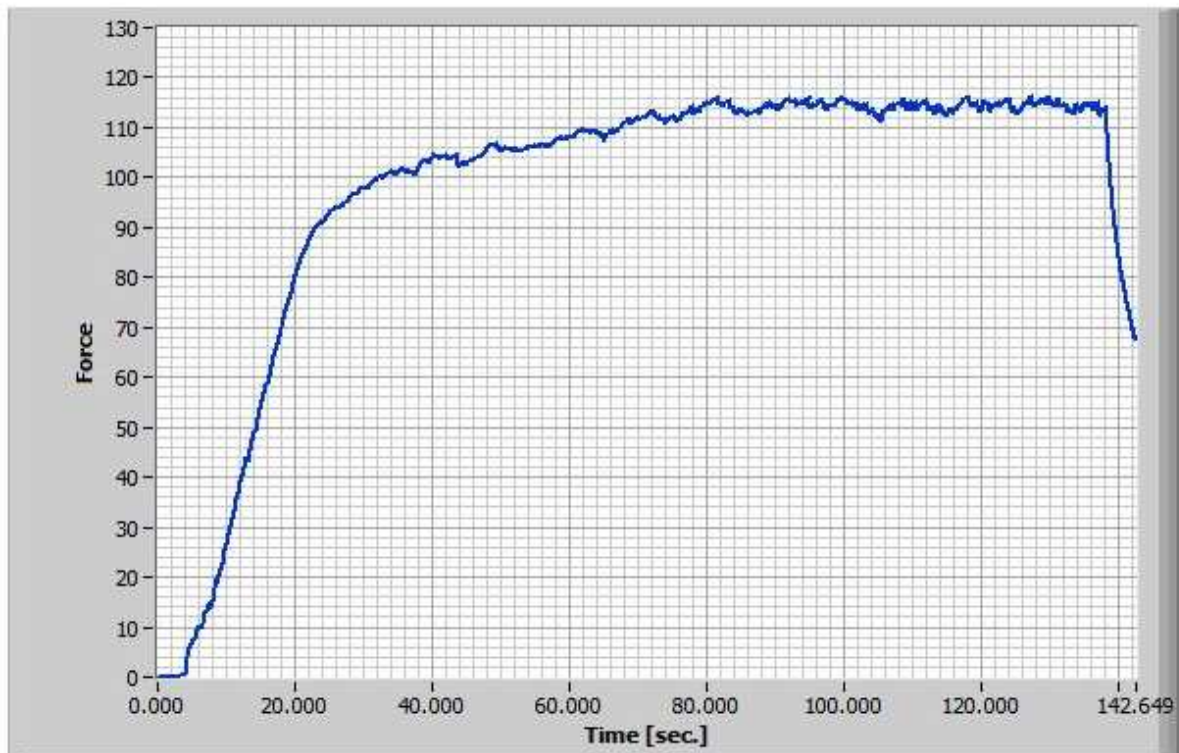
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 142.649

Statistics

Maximum: 116.2000
Minimum: 0.0000
Average: 97.4433
Area Under Curve: 13900.1876
Standard Deviation: 29.7647
Variance: 885.9401



1st L3-3.log

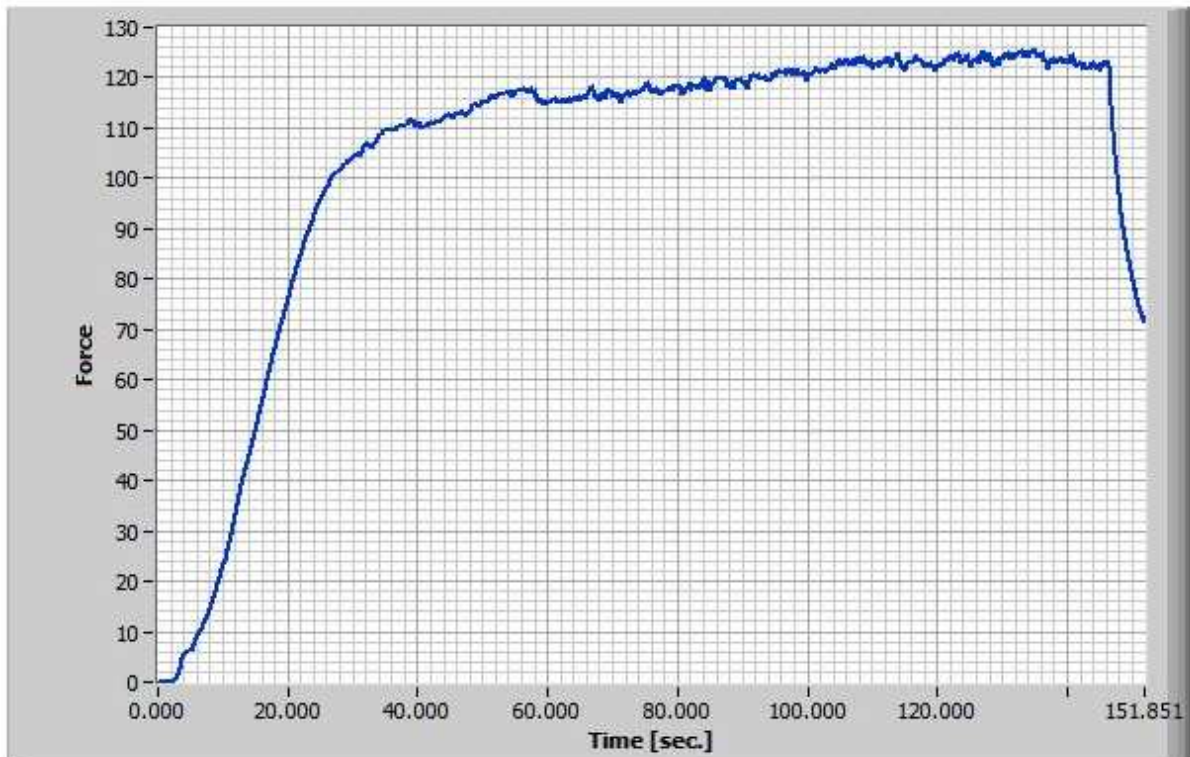
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 151.851

Statistics

Maximum: 125.6000
Minimum: 0.0000
Average: 104.1402
Area Under Curve: 15813.7892
Standard Deviation: 32.1028
Variance: 1030.5922



1st L1-1.log

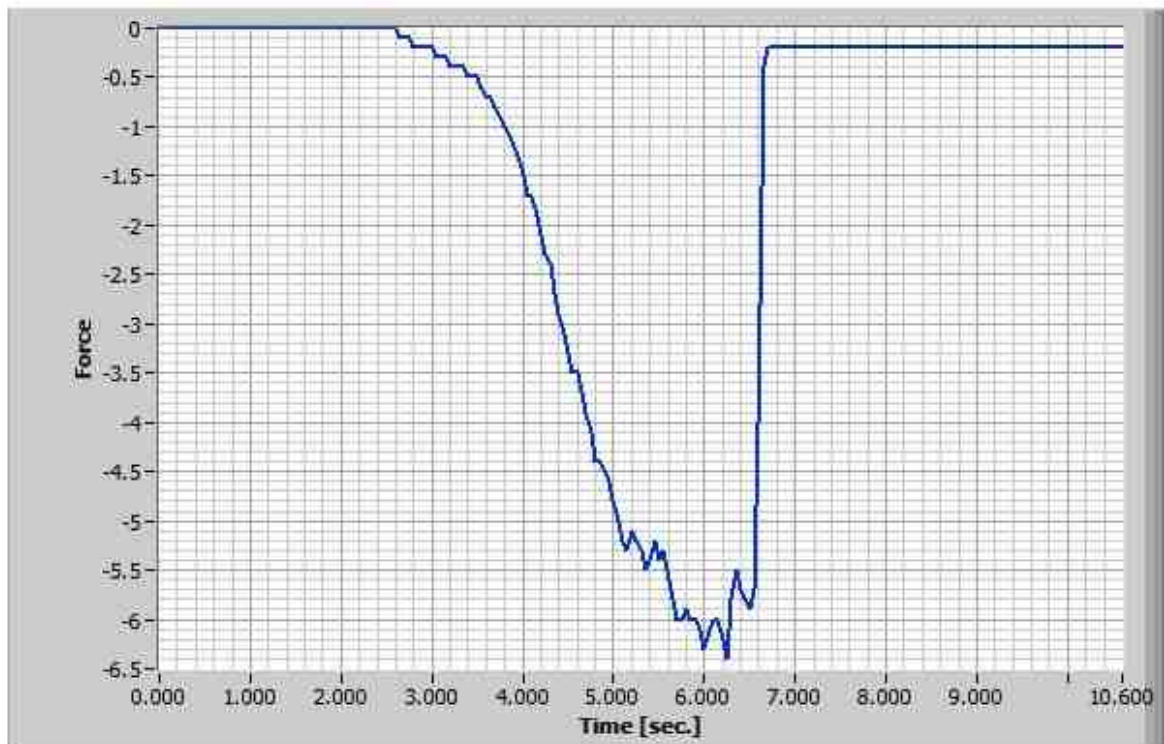
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 10.600

Statistics

Maximum: 0.0000
Minimum: -6.4000
Average: -1.3090
Area Under Curve: -13.8750
Standard Deviation: 2.0817
Variance: 4.3336



1st L1-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.751

Statistics

Maximum: 0.0000

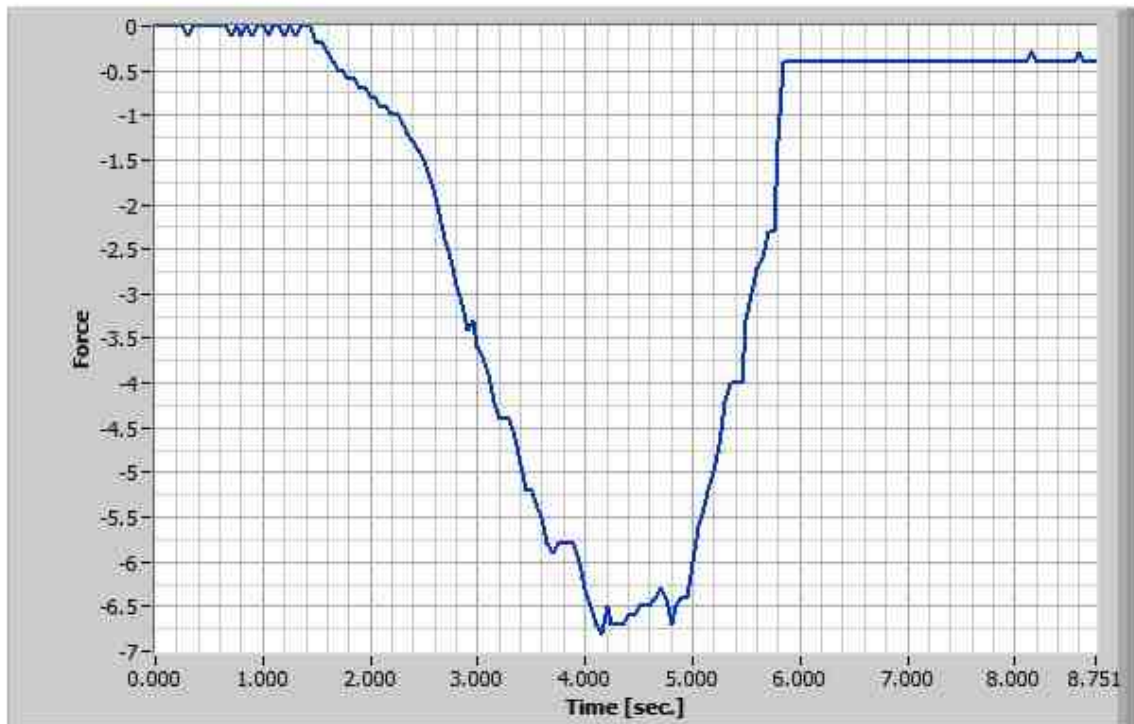
Minimum: -6.8000

Average: -2.0617

Area Under Curve: -18.0421

Standard Deviation: 2.3950

Variance: 5.7362



1st L1-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.800

Statistics

Maximum: 0.0000

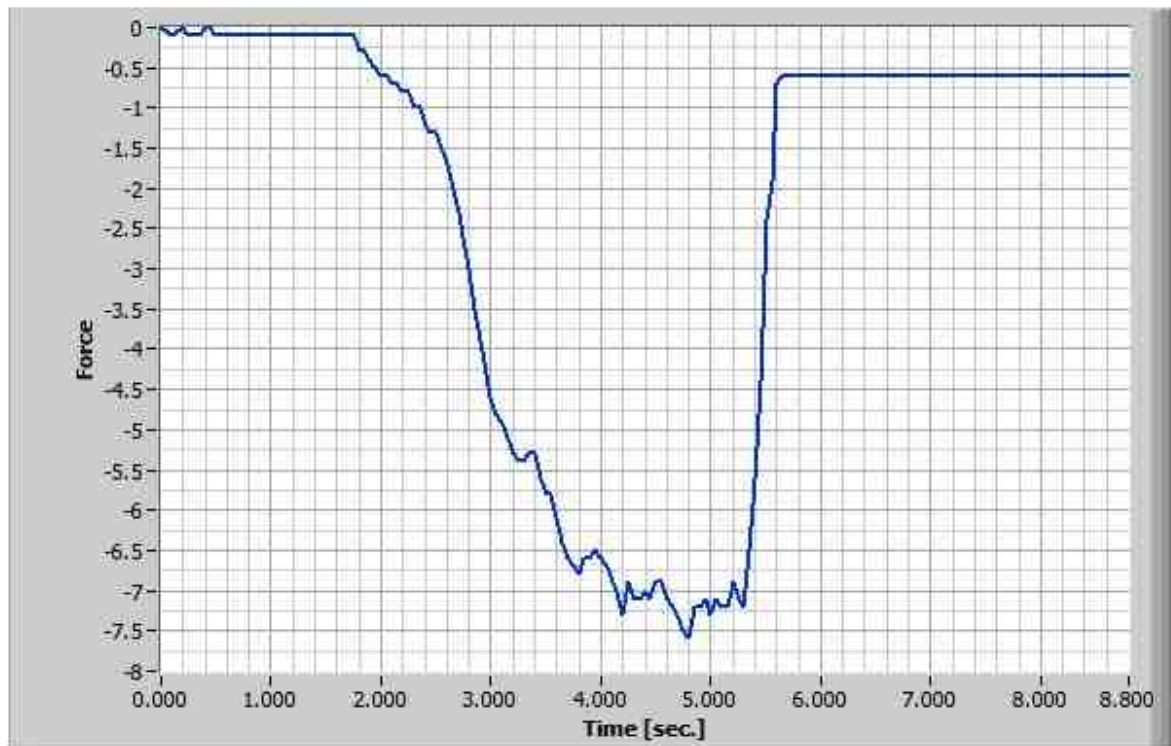
Minimum: -7.6000

Average: -2.3229

Area Under Curve: -20.4411

Standard Deviation: 2.7422

Variance: 7.5197



1st L2-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.199

Statistics

Maximum: 0.0000

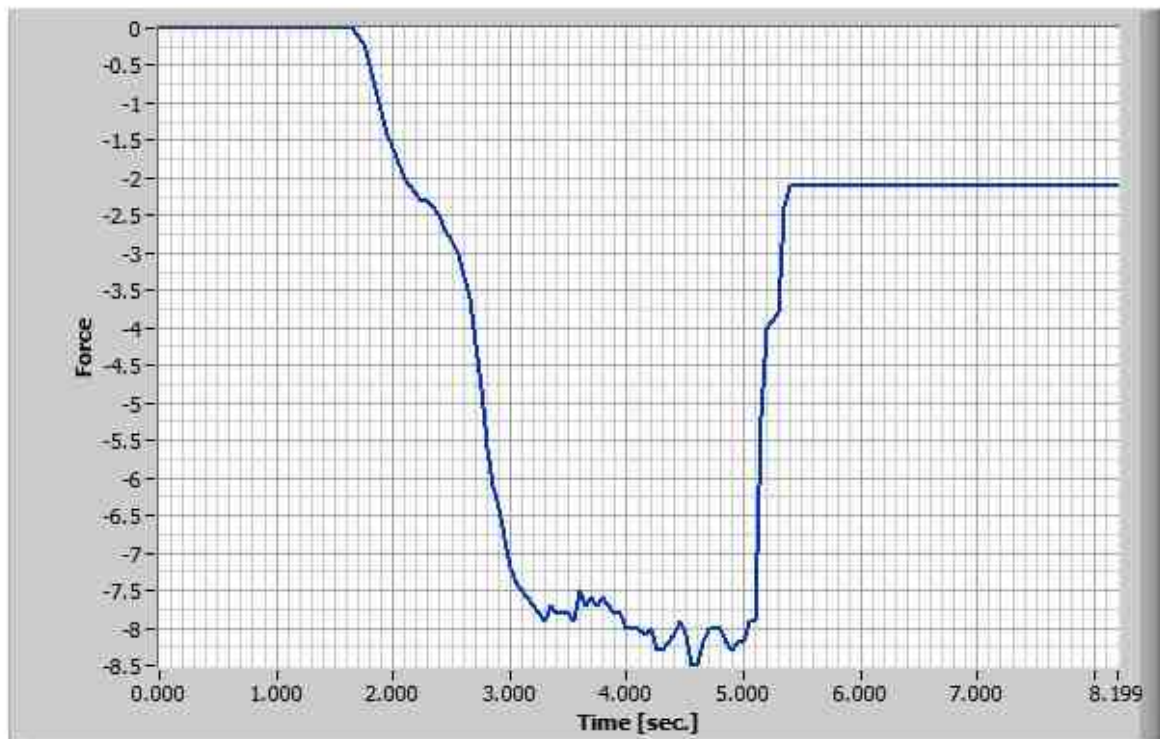
Minimum: -8.5000

Average: -3.3865

Area Under Curve: -27.7659

Standard Deviation: 2.9905

Variance: 8.9430



1st L2-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 7.501

Statistics

Maximum: 0.0000

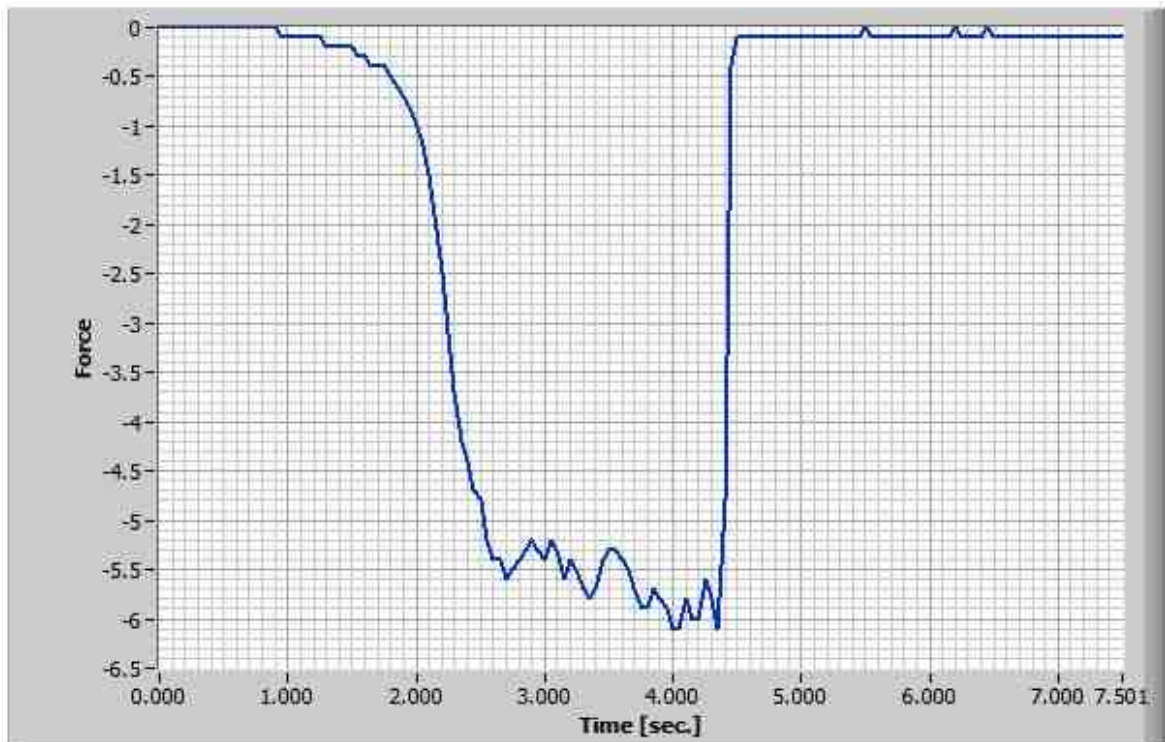
Minimum: -6.1000

Average: -1.7268

Area Under Curve: -12.9531

Standard Deviation: 2.4179

Variance: 5.8460



1st L2-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 7.899

Statistics

Maximum: 0.1000

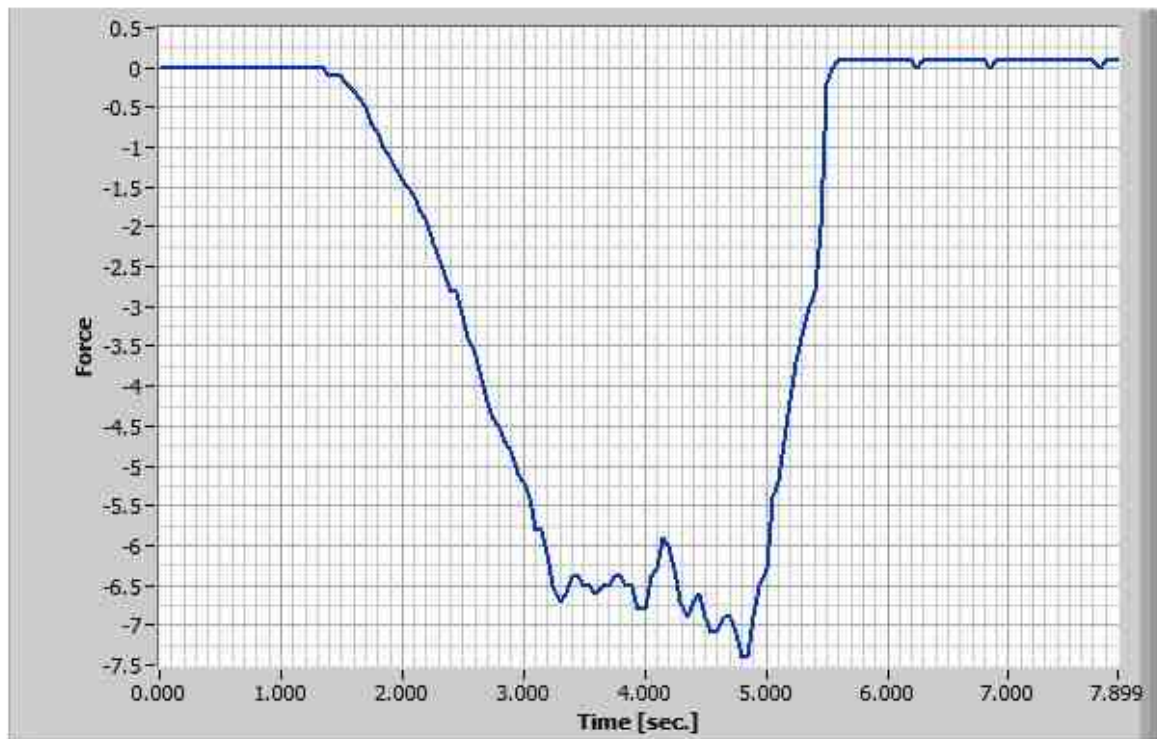
Minimum: -7.4000

Average: -2.3209

Area Under Curve: -18.3327

Standard Deviation: 2.8457

Variance: 8.0982



1st L3-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 7.550

Statistics

Maximum: 0.0000

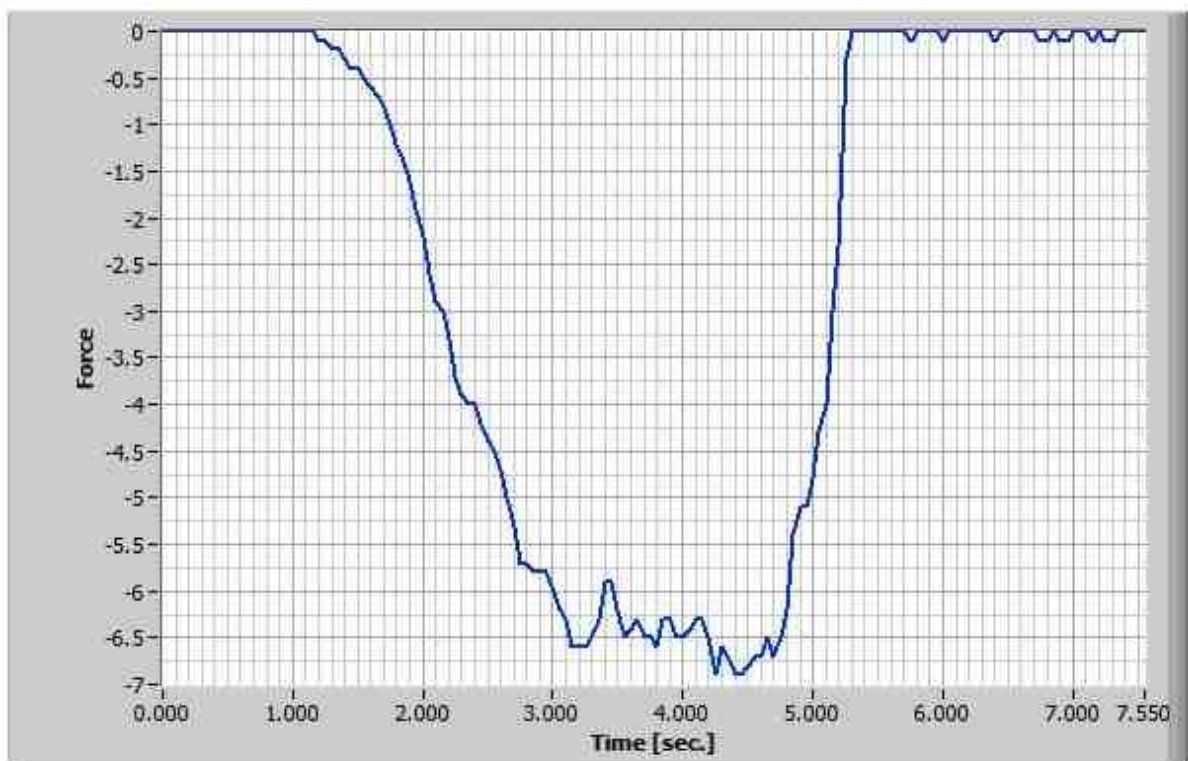
Minimum: -6.9000

Average: -2.4820

Area Under Curve: -18.7391

Standard Deviation: 2.8242

Variance: 7.9763



1st L3-2.log

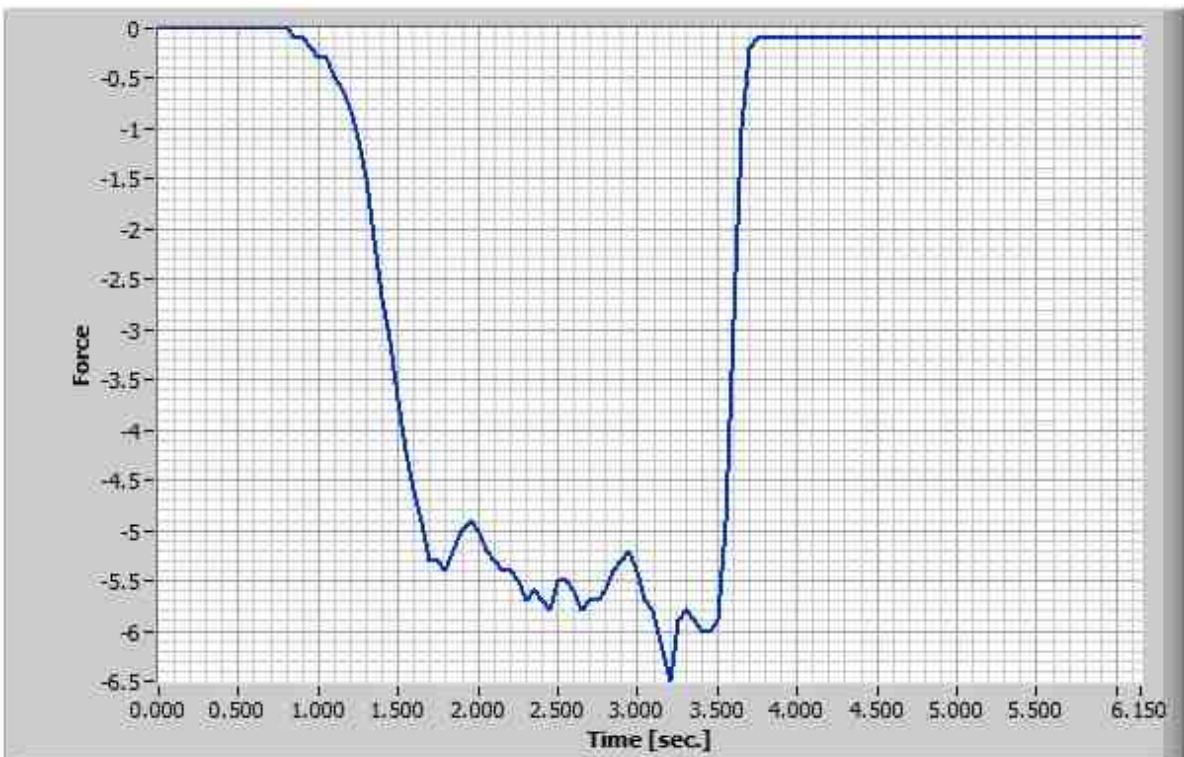
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 6.150

Statistics

Maximum: 0.0000
Minimum: -6.5000
Average: -2.0549
Area Under Curve: -12.6377
Standard Deviation: 2.5268
Variance: 6.3848



1st L3-3.log

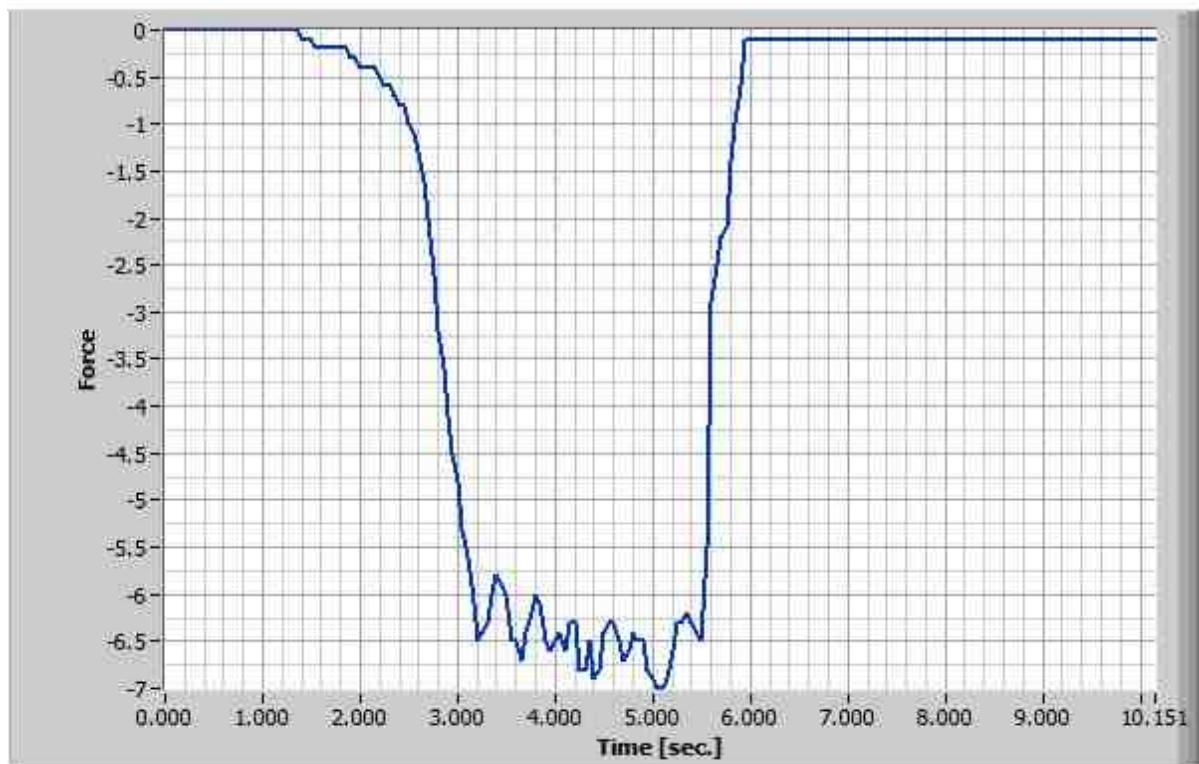
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 10.151




Statistics

Maximum: 0.0000
Minimum: -7.0000
Average: -1.9054
Area Under Curve: -19.3422
Standard Deviation: 2.7224
Variance: 7.4115

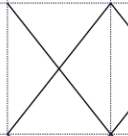
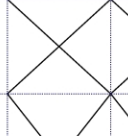
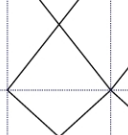
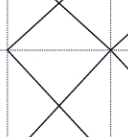



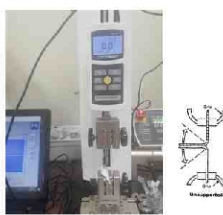
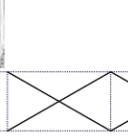


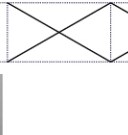


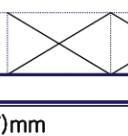





PERFORMANCE TEST CERTIFICATE

Written by 	Reviewed by 	Approved by 
07 / 19	/	07 / 19

제 품 명	Sterile Absorbable Hyaluronic Acid Dermal Filler	모 델 명	DENEBC-JC	Lot No	FDBIM3CXX160401
제조년월일	2016. 04. 12	검 사 자	Jeong, Eungjae	검 사 일	2016. 07. 19

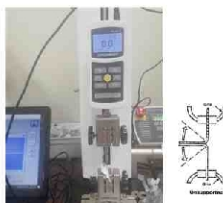



No	Inspection Item	Inspection Item	Inspection Criteria	Test Method	Inspection Level					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable		
		Packaging	Packaging should be free from scratches, twisting, pinhole.			Suitable	Suitable	Suitable		
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.83	6.85	6.83			
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.103	3.211	3.262			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	114.9	117.9	110.7			
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	5.8	7.0	6.4			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
					No Leak	No Leak	No Leak			
	No Leak	No Leak	No Leak							



PERFORMANCE TEST CERTIFICATE

Written by <i>[Signature]</i>	Reviewed by 	Approved by <i>[Signature]</i>
07 / 19	/	07 / 19

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160501
Date of manufacture	2016. 05. 03	Tester	Jeong, Eungjae	Inspection Date	2016. 07. 19

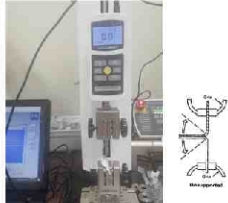



No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable	 	
		Packaging				Packaging should be free from scratches, twisting, pinhole.	Suitable	Suitable		
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.85	6.84	6.84	 	 	
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.218	3.217	3.208			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	112.8	109.5	108.5	 	 	
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	7.5	6.5	6.3			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
					No Leak	No Leak	No Leak	 	 	
						No Leak	No Leak			No Leak



PERFORMANCE TEST CERTIFICATE

Written by <i>[Signature]</i>	Reviewed by 	Approved by <i>[Signature]</i>
07 / 19	/	07 / 19

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160502
Date of manufacture	2016.05.27	Tester	Jeong, Eungjae	Inspection Date	2016. 07. 19

No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable	 	
		Packaging				Packaging should be free from scratches, twisting, pinhole.	Suitable	Suitable		
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.82	6.83	6.82	 	 	
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.123	3.234	3.122			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	112.9	114.4	113.9	 	 	
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	6.2	6.1	7.2			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
						No Leak	No Leak	No Leak	 	
	No Leak	No Leak	No Leak	 	 					

2nd L1-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 116.050

Statistics

Maximum: 114.9000

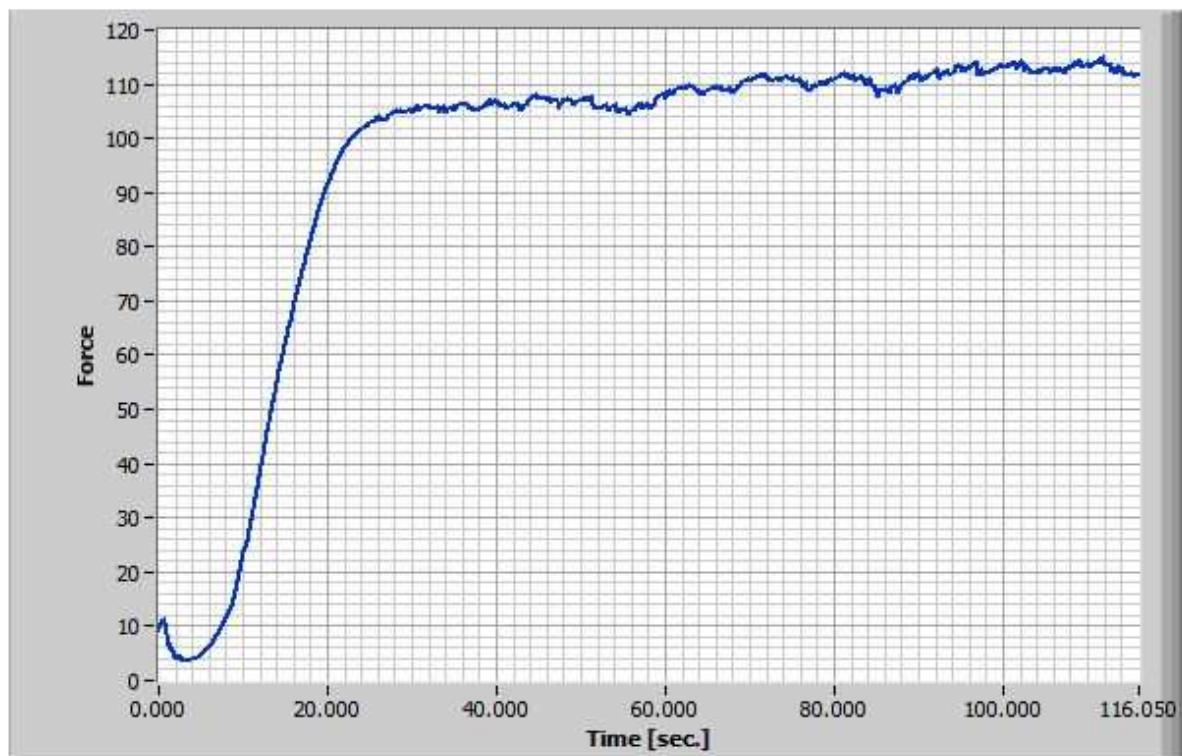
Minimum: 3.8000

Average: 95.8706

Area Under Curve: 11125.7850

Standard Deviation: 30.9040

Variance: 955.0541



2nd L1-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 136.350

Statistics

Maximum: 117.9000

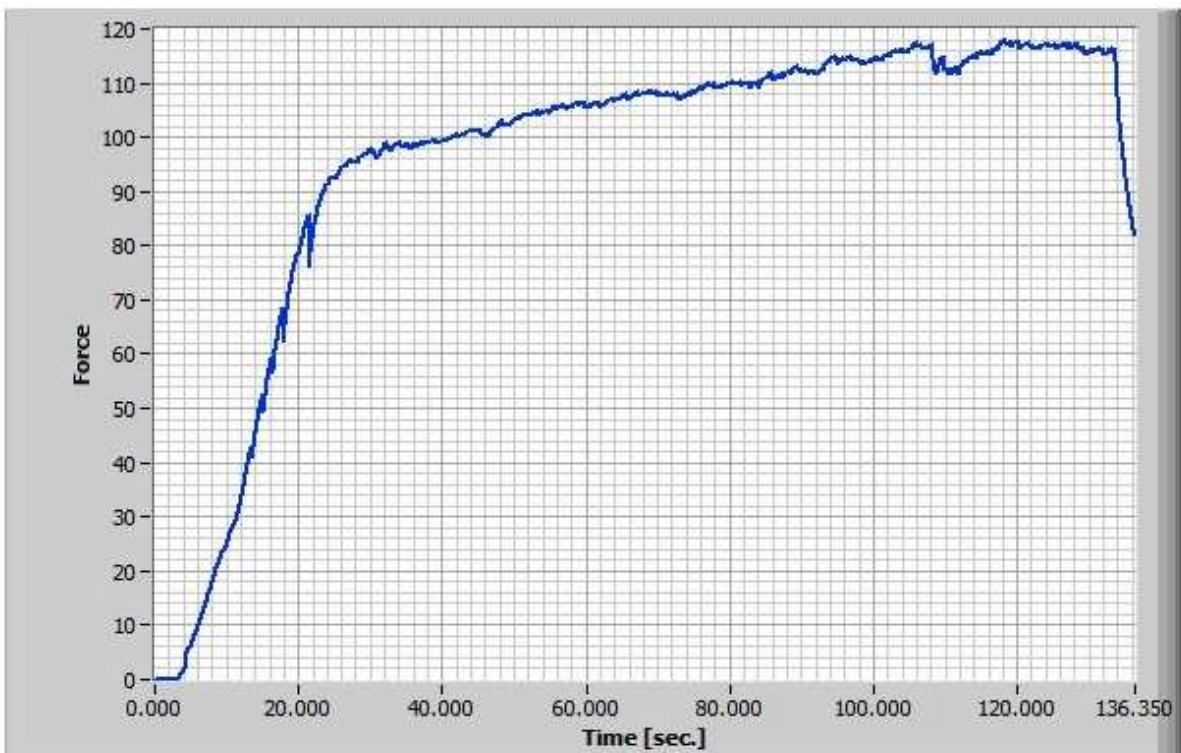
Minimum: 0.0000

Average: 96.1256

Area Under Curve: 13106.7313

Standard Deviation: 30.0555

Variance: 903.3306



2nd L1-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 127.250

Statistics

Maximum: 110.7000

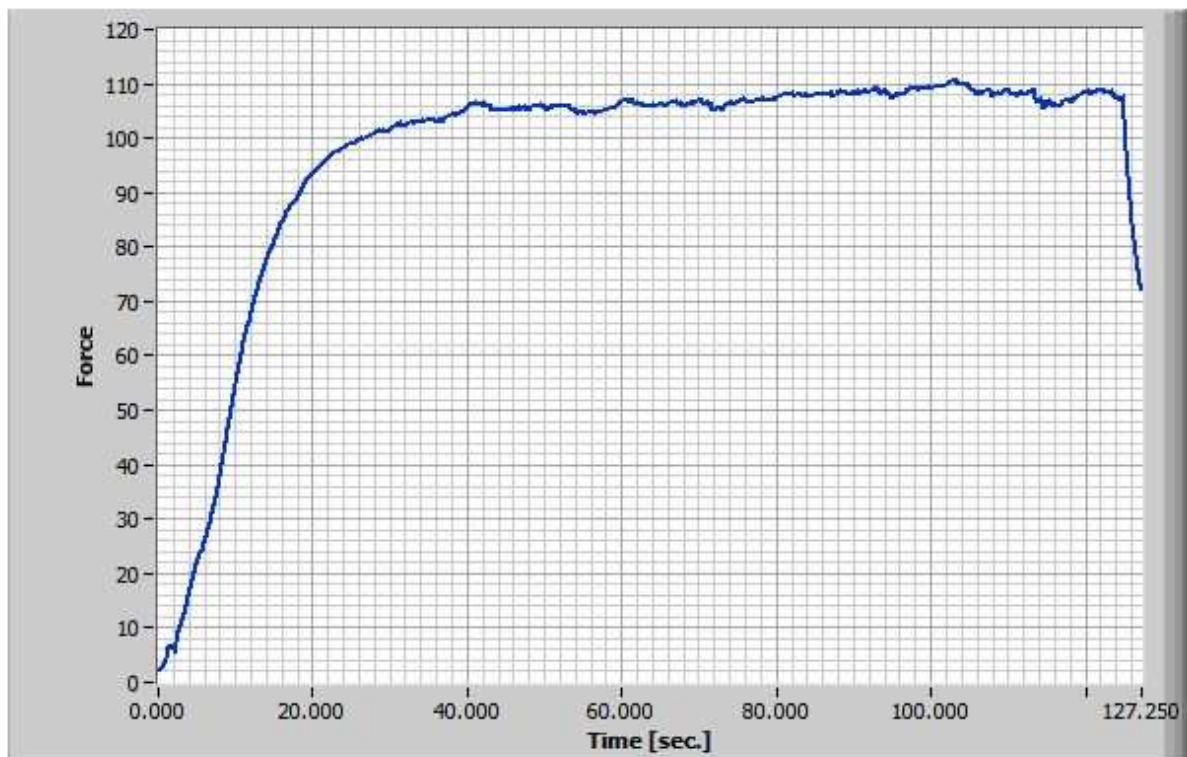
Minimum: 2.1000

Average: 97.0575

Area Under Curve: 12350.5679

Standard Deviation: 23.6606

Variance: 559.8230



2nd L2-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 140.499

Statistics

Maximum: 112.8000

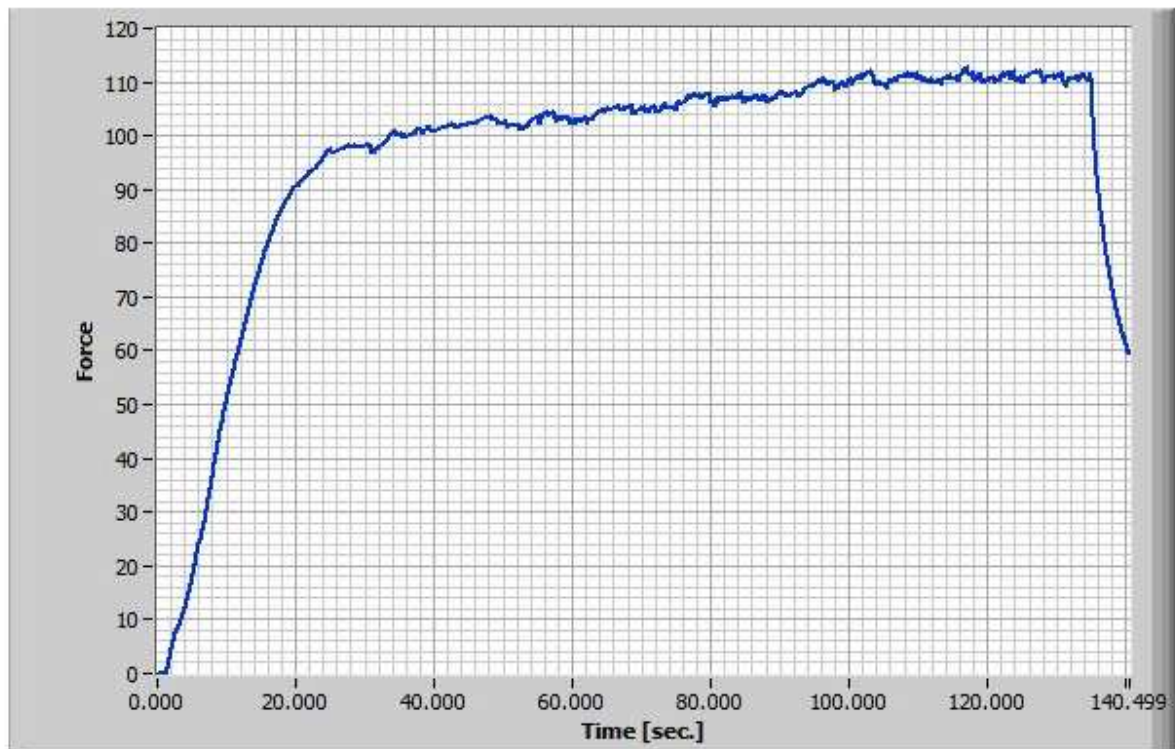
Minimum: 0.0000

Average: 96.2647

Area Under Curve: 13525.1002

Standard Deviation: 24.1214

Variance: 581.8414



2nd L2-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 158.450

Statistics

Maximum: 109.5000

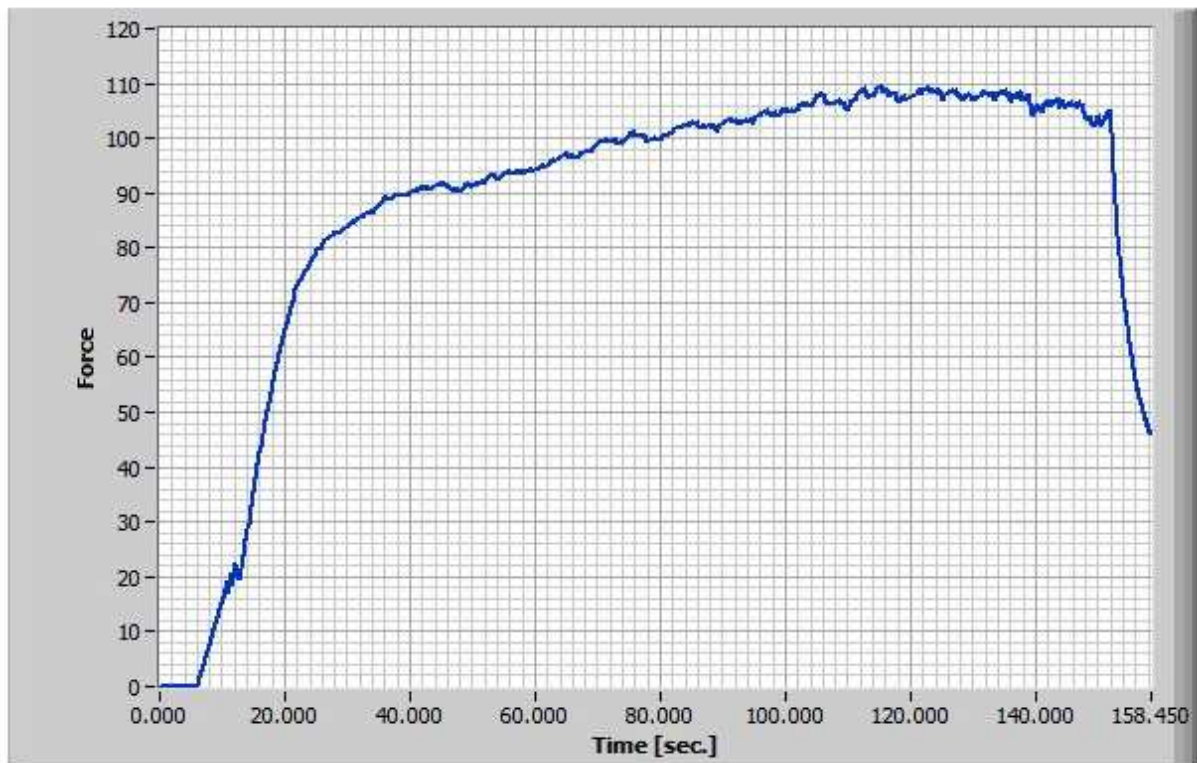
Minimum: 0.0000

Average: 87.7352

Area Under Curve: 13901.6368

Standard Deviation: 28.9431

Variance: 837.7053



2nd L2-3.log

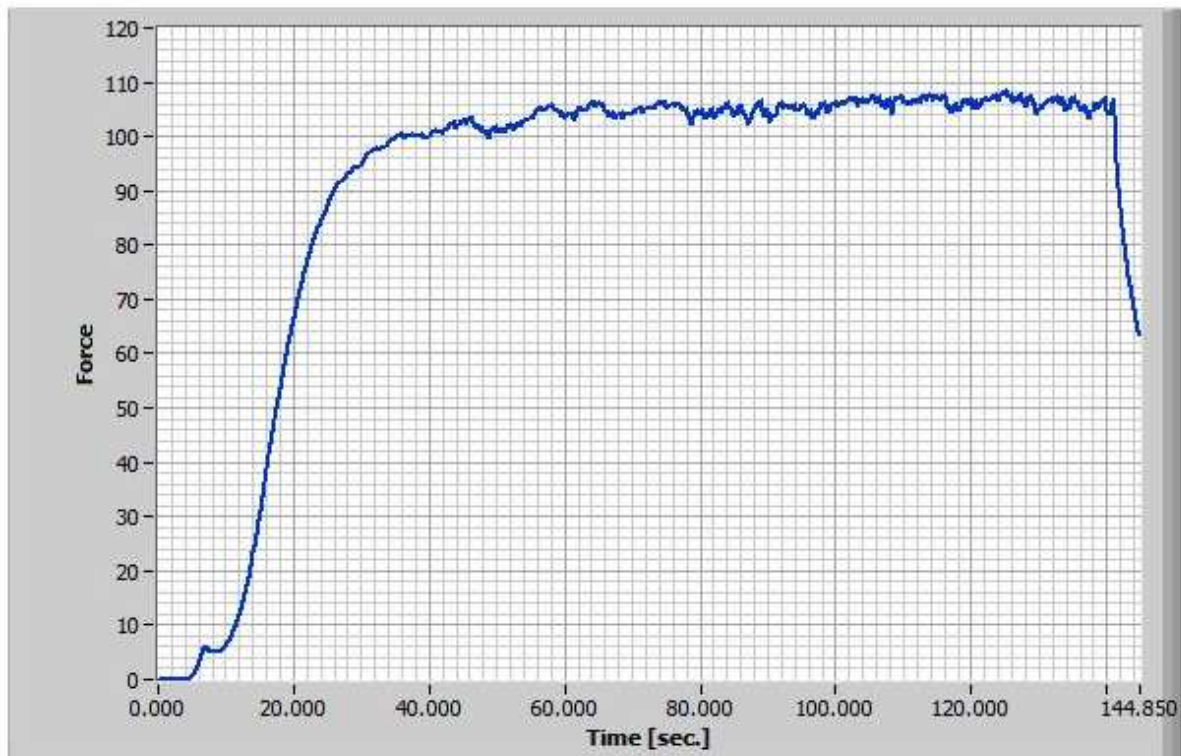
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 144.850

Statistics

Maximum: 108.5000
Minimum: 0.0000
Average: 90.4368
Area Under Curve: 13099.7700
Standard Deviation: 31.0554
Variance: 964.4349



2nd L3-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 136.650

Statistics

Maximum: 112.9000

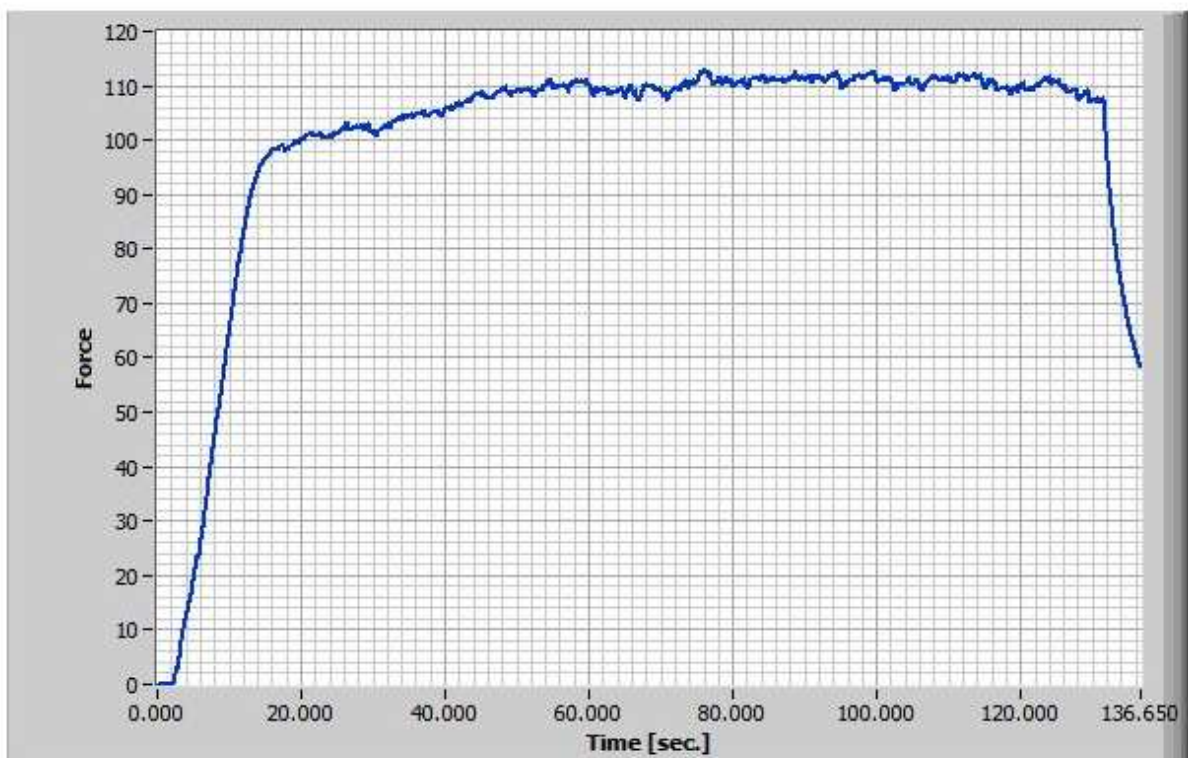
Minimum: 0.0000

Average: 100.0029

Area Under Curve: 13665.4001

Standard Deviation: 23.9607

Variance: 574.1134



2nd L3-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 142.807

Statistics

Maximum: 114.4000

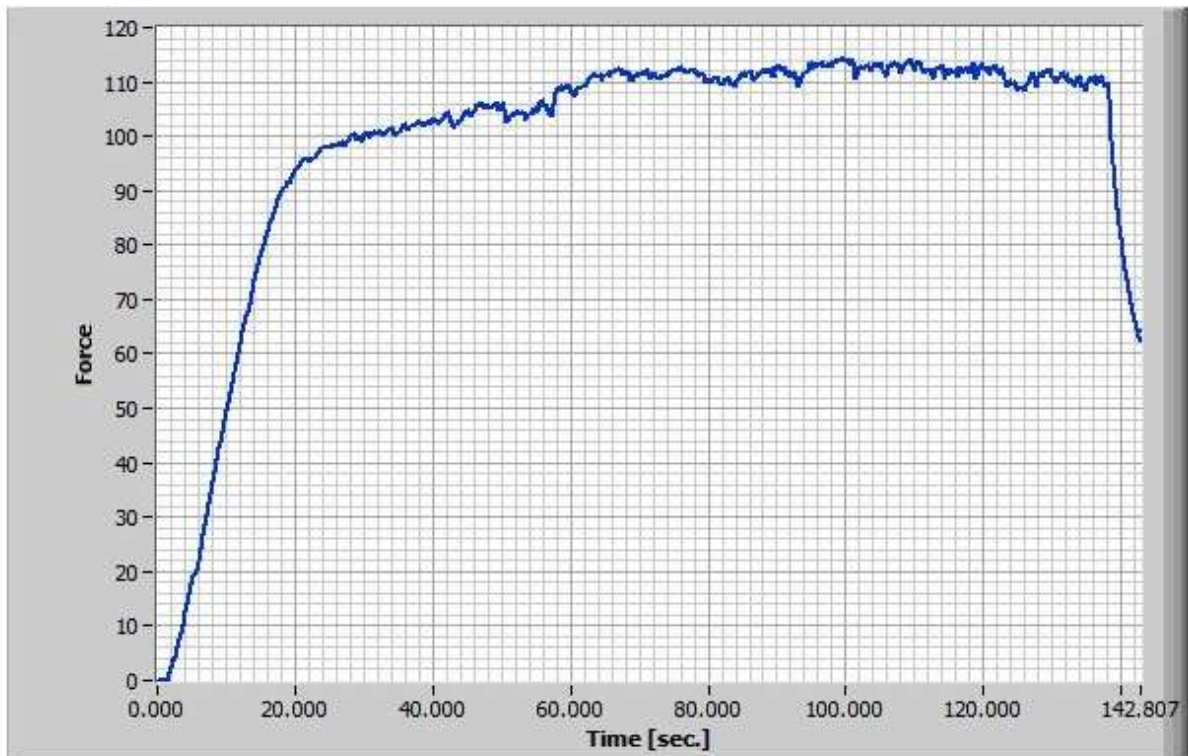
Minimum: 0.0000

Average: 98.8981

Area Under Curve: 14123.3421

Standard Deviation: 24.9055

Variance: 620.2819



2nd L3-3.log

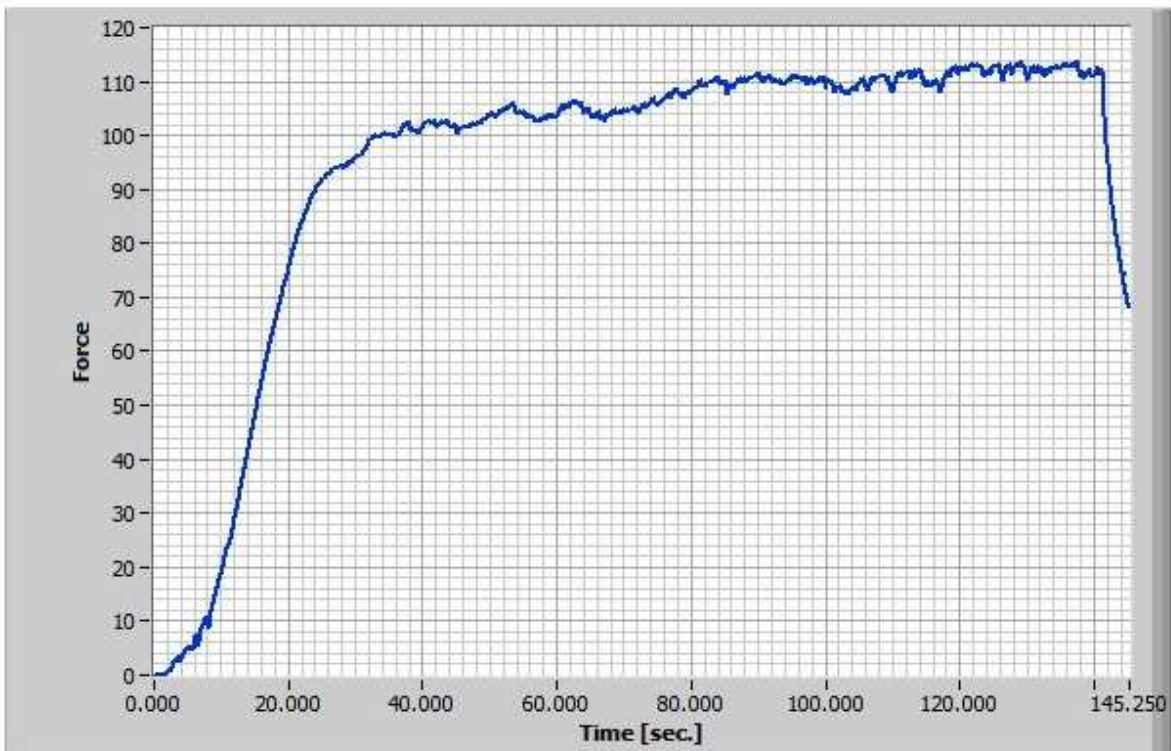
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 145.250

Statistics

Maximum: 113.9000
Minimum: 0.0000
Average: 94.5198
Area Under Curve: 13729.0060
Standard Deviation: 29.4468
Variance: 867.1152



2nd L1-1.log

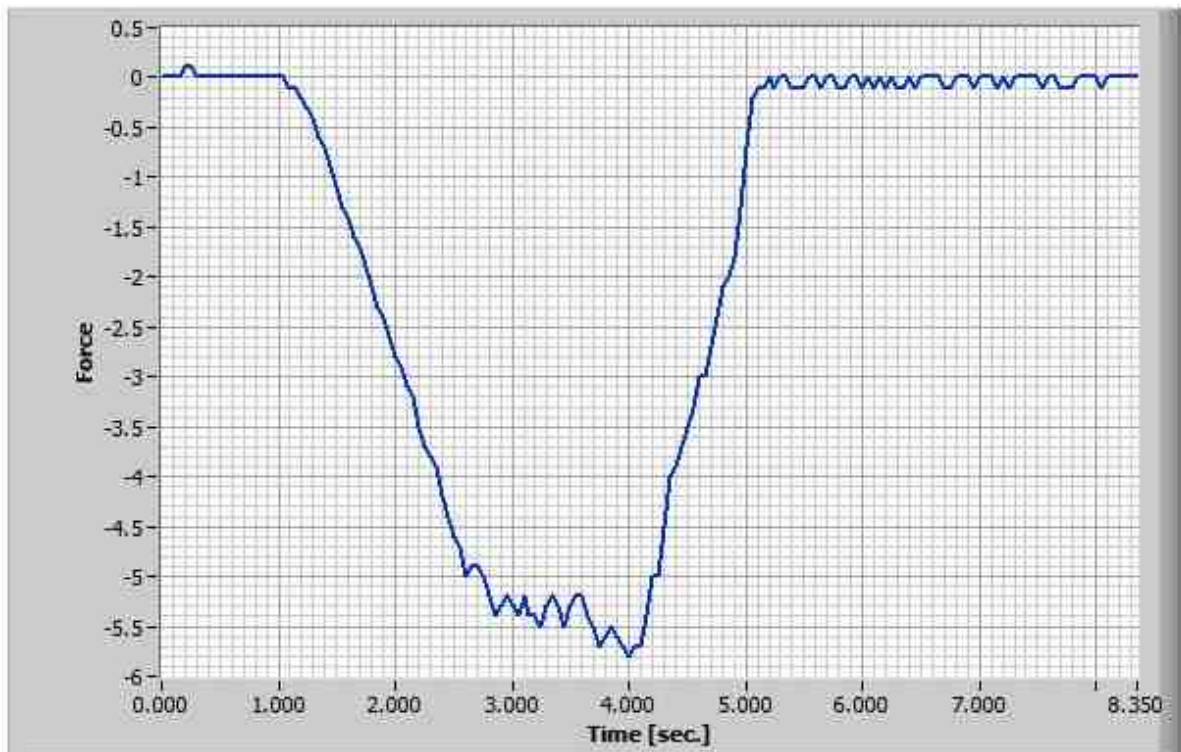
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 8.350

Statistics

Maximum: 0.1000
Minimum: -5.8000
Average: -1.7627
Area Under Curve: -14.7181
Standard Deviation: 2.2030
Variance: 4.8531



2nd L1-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 7.400

Statistics

Maximum: 0.0000

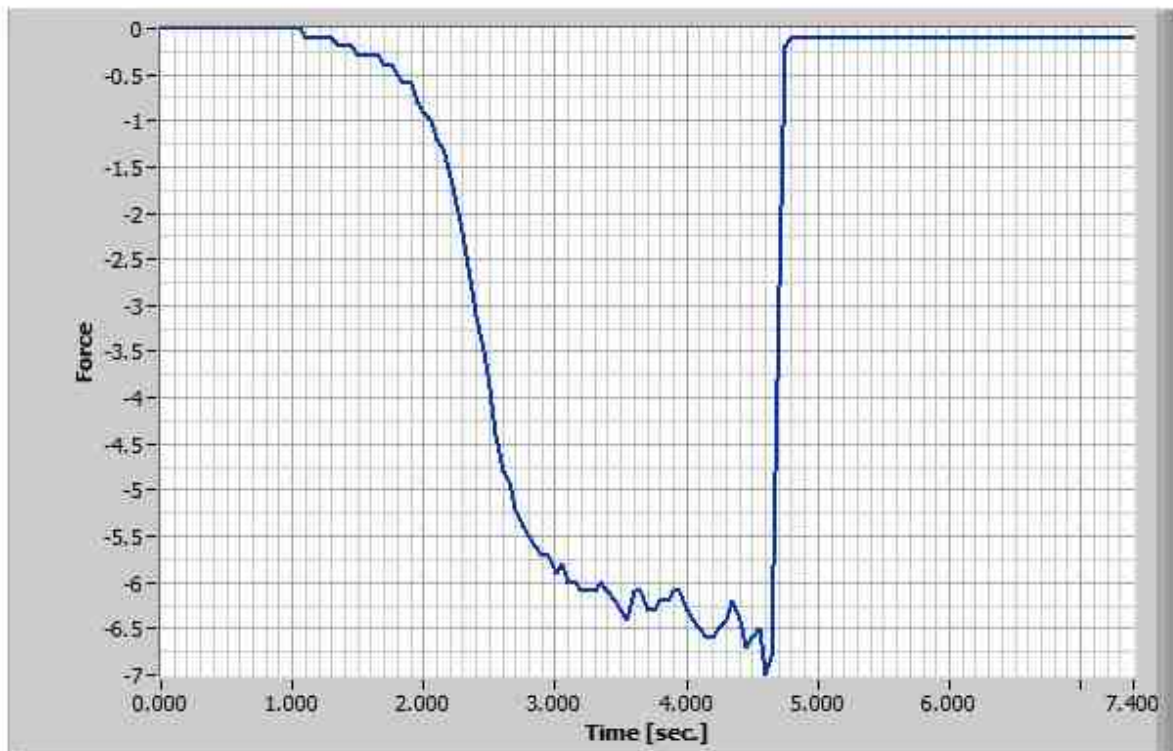
Minimum: -7.0000

Average: -2.0293

Area Under Curve: -15.0165

Standard Deviation: 2.6984

Variance: 7.2815



2nd L1-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.950

Statistics

Maximum: 0.0000

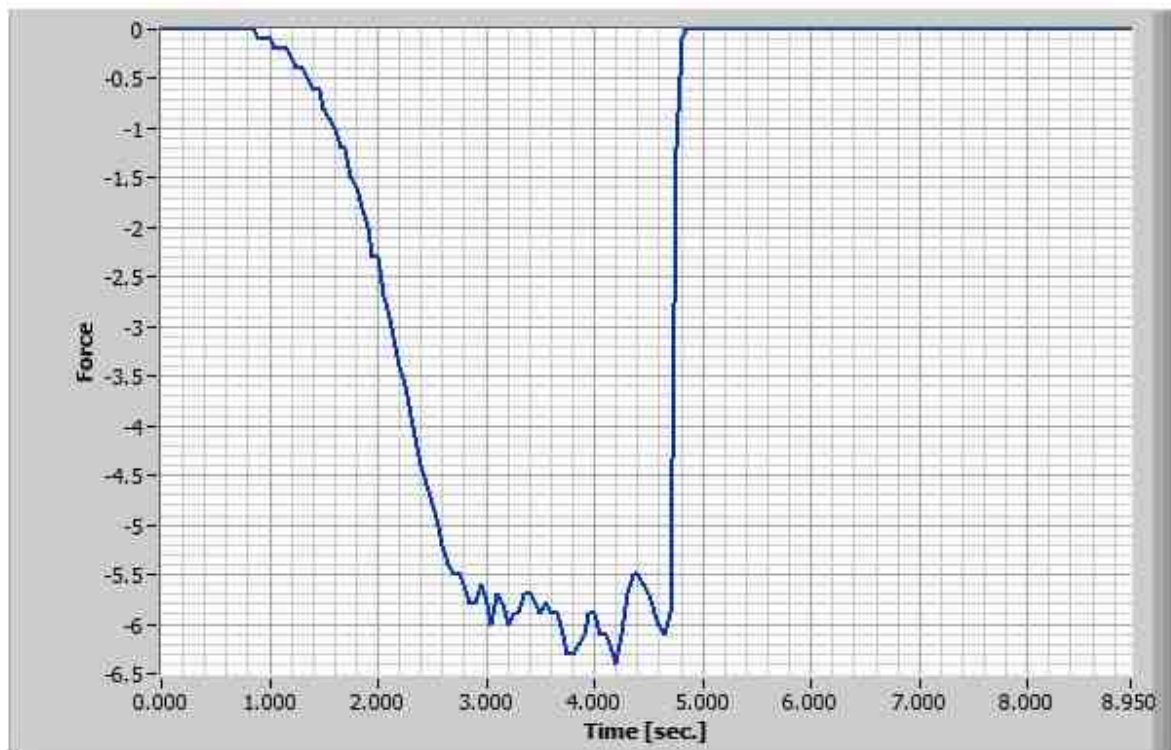
Minimum: -6.4000

Average: -1.7648

Area Under Curve: -15.7950

Standard Deviation: 2.5097

Variance: 6.2988



2nd L2-1.log

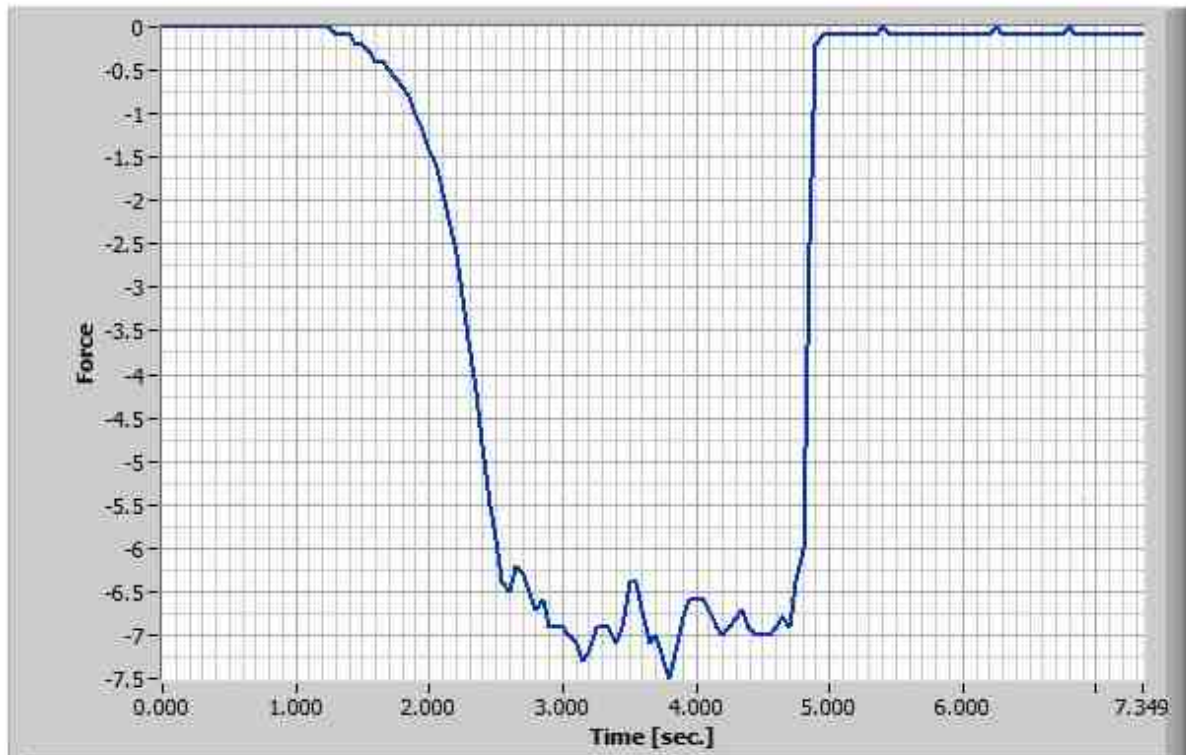
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 7.349

Statistics

Maximum: 0.0000
Minimum: -7.5000
Average: -2.4932
Area Under Curve: -18.3222
Standard Deviation: 3.0962
Variance: 9.5864



2nd L2-2.log

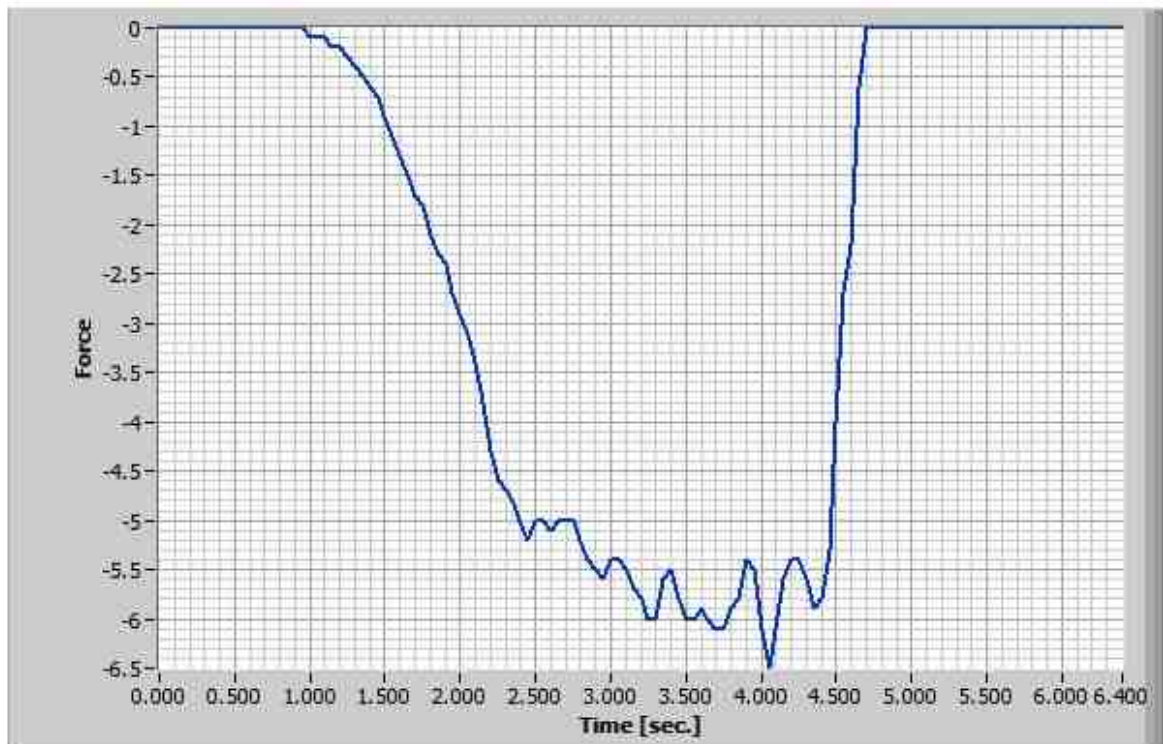
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 6.400

Statistics

Maximum: 0.0000
Minimum: -6.5000
Average: -2.3402
Area Under Curve: -14.9770
Standard Deviation: 2.5514
Variance: 6.5099



2nd L2-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 9.600

Statistics

Maximum: 0.0000

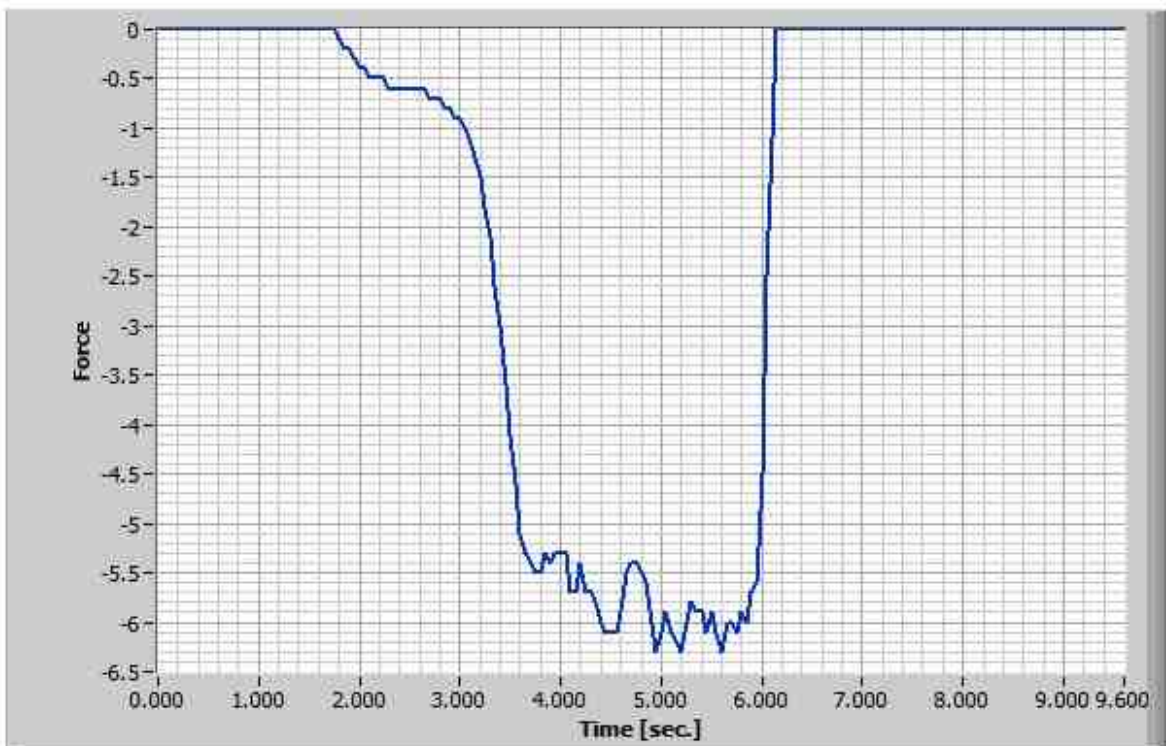
Minimum: -6.3000

Average: -1.7063

Area Under Curve: -16.3803

Standard Deviation: 2.4779

Variance: 6.1402



2nd L3-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 7.650

Statistics

Maximum: 0.0000

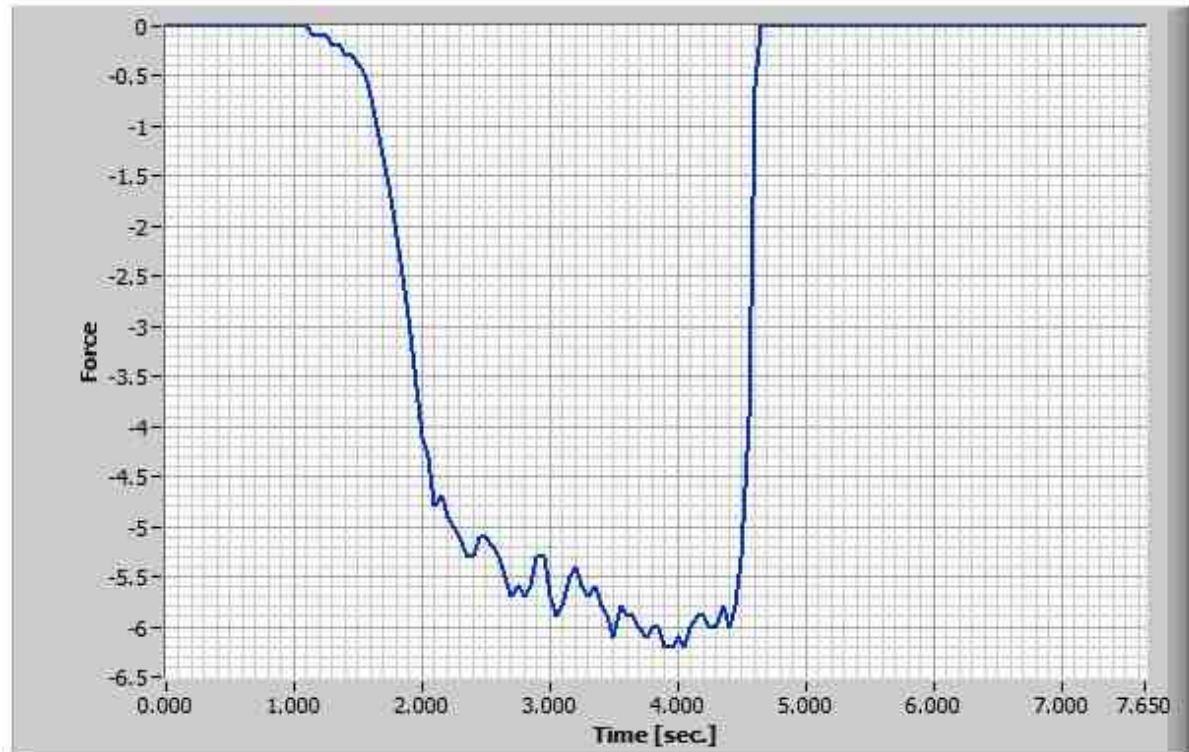
Minimum: -6.2000

Average: -2.0230

Area Under Curve: -15.4762

Standard Deviation: 2.6199

Variance: 6.8636



2nd L3-2.log

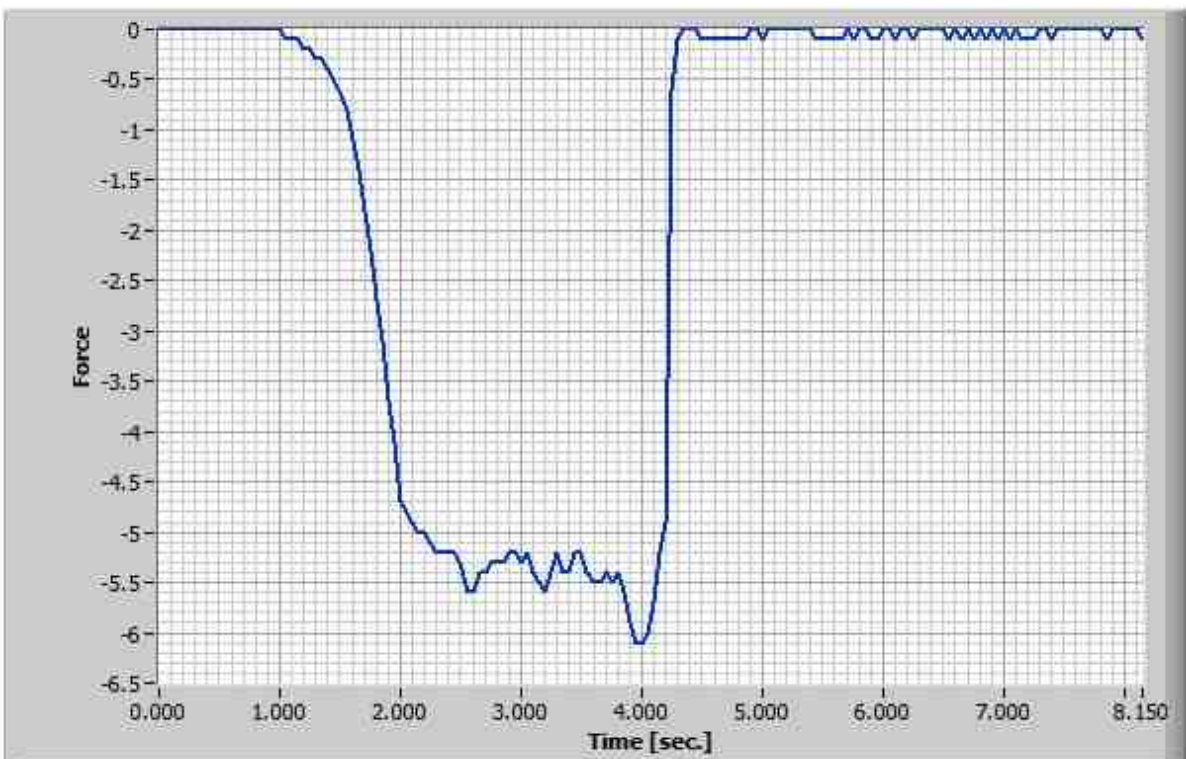
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 8.150

Statistics

Maximum: 0.0000
Minimum: -6.1000
Average: -1.6568
Area Under Curve: -13.5028
Standard Deviation: 2.3774
Variance: 5.6522



2nd L3-3.log

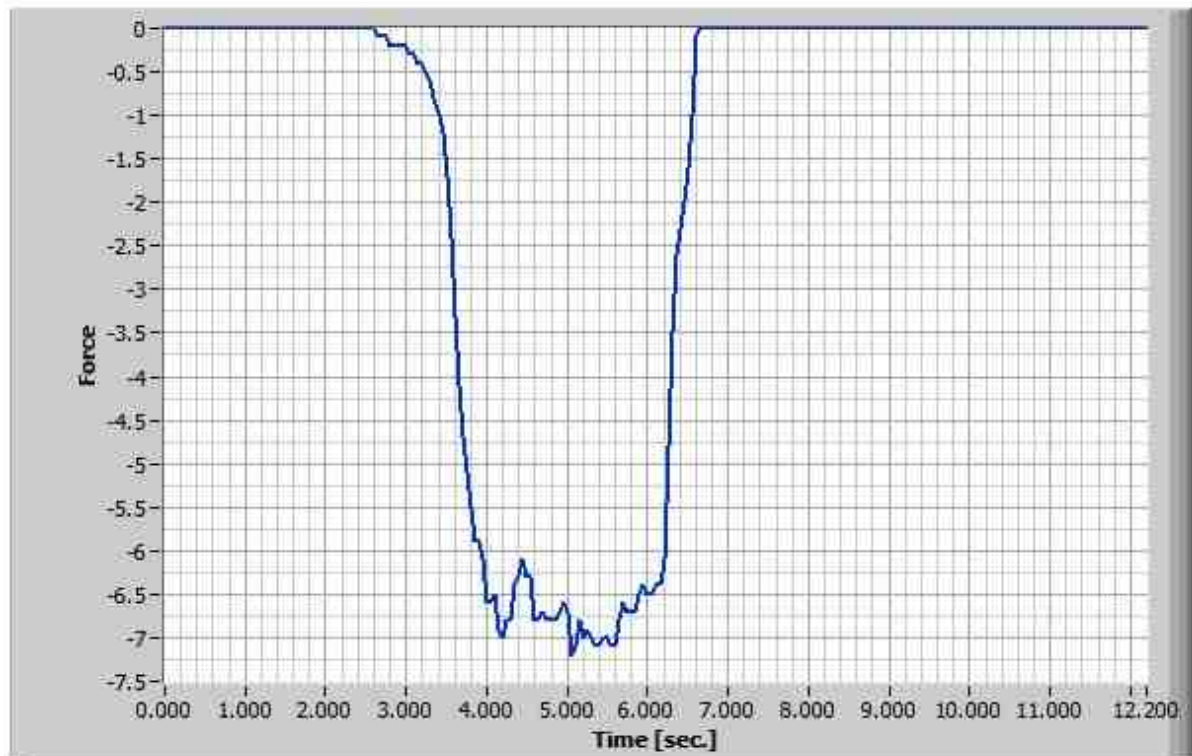
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 12.200

Statistics

Maximum: 0.0000
Minimum: -7.2000
Average: -1.5284
Area Under Curve: -18.6464
Standard Deviation: 2.6840
Variance: 7.2041

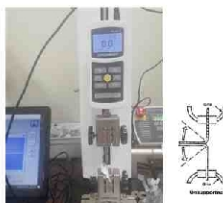







PERFORMANCE TEST CERTIFICATE

Written by	Reviewed by	Approved by
9 / 21	/	9 / 21

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160401
Date of manufacture	2016. 04. 12	Tester	Jeong, Eungjae	Inspection Date	2016. 09. 21

No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable		
		Packaging				Packaging should be free from scratches, twisting, pinhole.	Suitable	Suitable	Suitable	
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.74	6.75	6.70			
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.323	3.319	3.118			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	104.3	116.2	103.1			
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	5.6	7.8	6.1			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
						No Leak	No Leak	No Leak		
						No Leak	No Leak	No Leak		



PERFORMANCE TEST CERTIFICATE

Written by 	Reviewed by 	Approved by
9 / 21	/	9 / 21

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160501
Date of manufacture	2016. 05. 03	Tester	Jeong, Eungjae	Inspection Date	2016. 09. 21

No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements						
					X1	X2	X3	X4	X5		
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable			
		Packaging				Packaging should be free from scratches, twisting, pinhole.	Suitable	Suitable	Suitable		
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.68	6.70	6.69				
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.122	3.185	3.316				
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	112.6	109.5	102.4				
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	6.3	6.5	7.1				
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo						
						No Leak	No Leak	No Leak			
							No Leak	No Leak	No Leak		



PERFORMANCE TEST CERTIFICATE

Written by 	Reviewed by 	Approved by
9 / 21	/	9 / 21

Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Model	DENEB-JC	Lot No	FDBIM3CXX160502
Date of manufacture	2016.05.27	Tester	Jeong, Eungjae	Inspection Date	2016. 09. 21

No	Inspection Item	Inspection Criteria	Test Method	Inspection Level	Measurements					
					X1	X2	X3	X4	X5	
1	Appearance Test	Product	The content must be clear, transparent and viscous gel with no foreign object to the naked eye.	Test according to Report 9	n=3 c=0	Suitable	Suitable	Suitable		
		Packaging				Packaging should be free from scratches, twisting, pinhole.	Suitable	Suitable	Suitable	
2	pH Test	☞ When tested in accordance with test method, pH should be 5.5 ~ 8.5.	Test according to Report 9	n=3 c=0	6.73	6.73	6.72			
3	Actual Volume Test	☞ When tested in accordance with test method, it should be more than 3g. (But., 1g is 1ml.)	Test according to Report 9	n=3 c=0	3.332	3.218	3.274			
4	Injection Force Test	☞ When measuring the maximum value (N), injection force should be between 80 and 130N.	Test according to Report 9	n=3 c=0	106.9	112.2	110.7			
5	Adhesive strength Test	☞ When tested in accordance with test method, it should be more than 5.0N/25.4mm. 	Test according to Report 9	n=3 c=0	5.6	5.6	6.4			
6	Dye penetration Test	☞ When observing dye for 30 sec. and 1 min., it should not leak. 	Test according to Report 9	n=3 c=0	☞ Dye Penetration Test Photo					
						No Leak	No Leak	No Leak		
						No Leak	No Leak	No Leak		

3rd L1-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 136.551

Statistics

Maximum: 104.3000

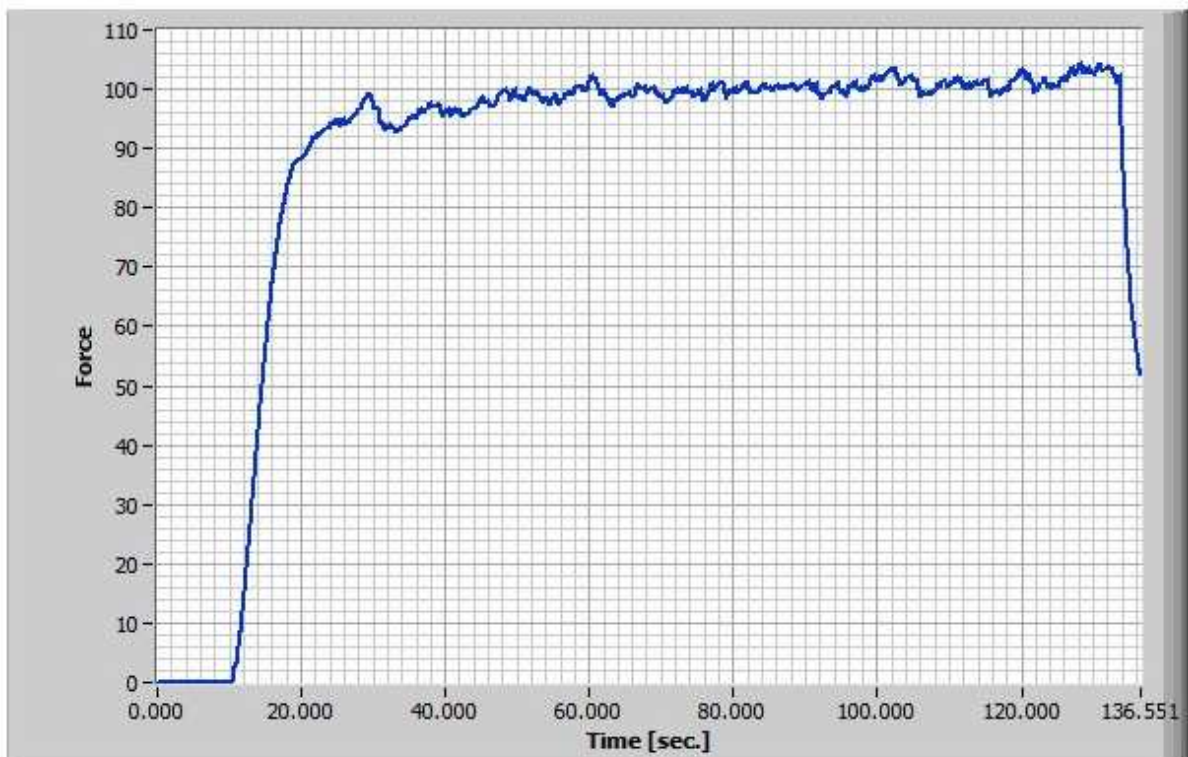
Minimum: 0.0000

Average: 87.7275

Area Under Curve: 11979.2841

Standard Deviation: 29.3443

Variance: 861.0887



3rd L1-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 133.499

Statistics

Maximum: 116.2000

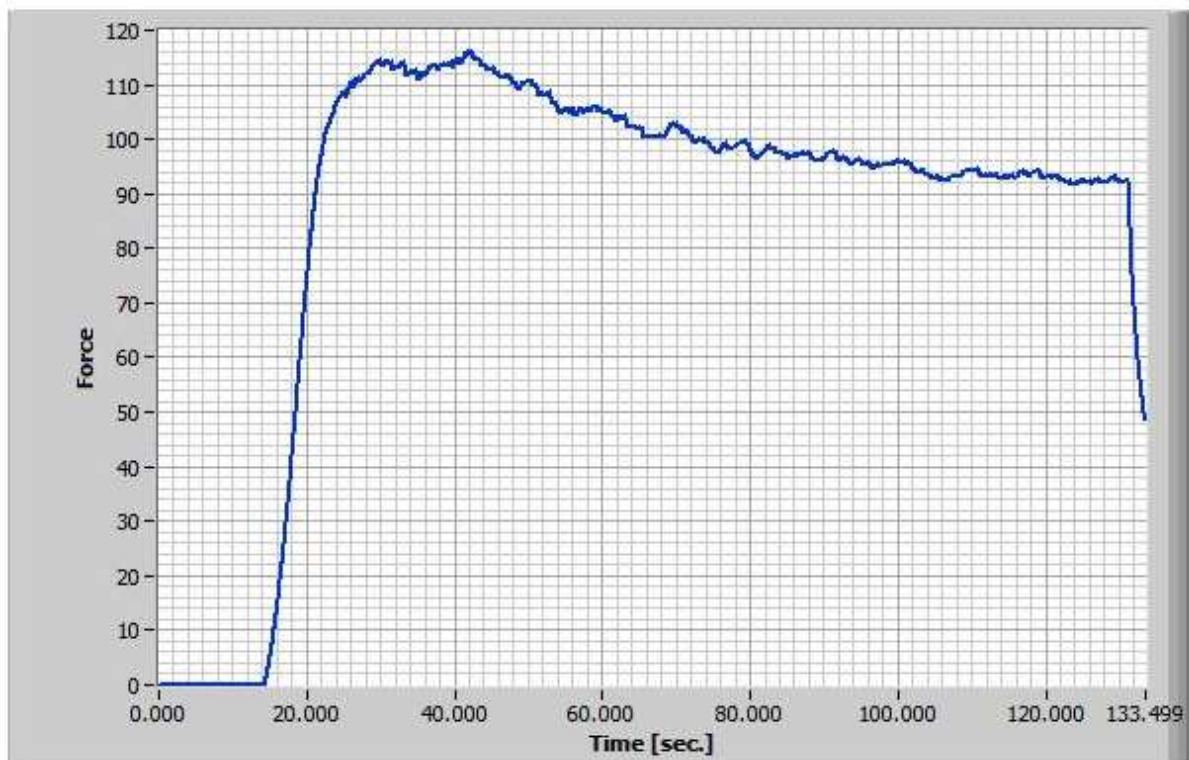
Minimum: 0.0000

Average: 86.6210

Area Under Curve: 11563.8194

Standard Deviation: 34.4123

Variance: 1184.2071



3rd L1-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 134.600

Statistics

Maximum: 103.1000

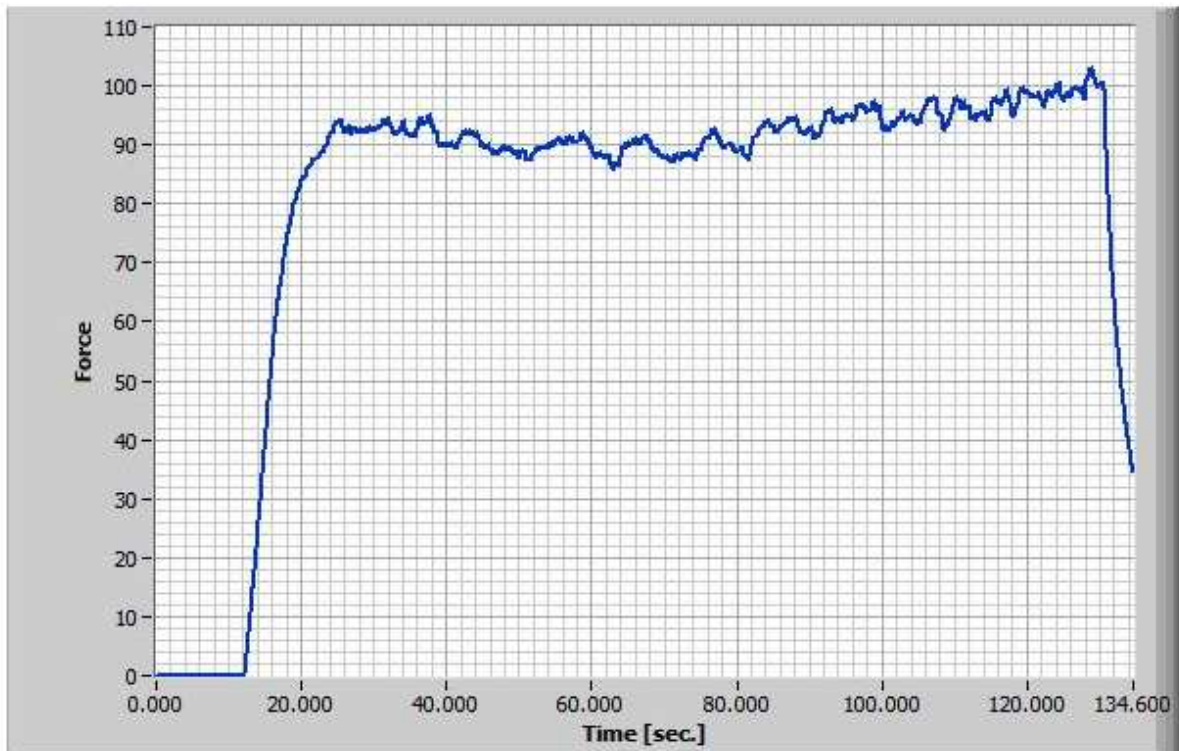
Minimum: 0.0000

Average: 80.8327

Area Under Curve: 10880.0816

Standard Deviation: 28.9258

Variance: 836.7046



3rd L2-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 144.899

Statistics

Maximum: 112.6000

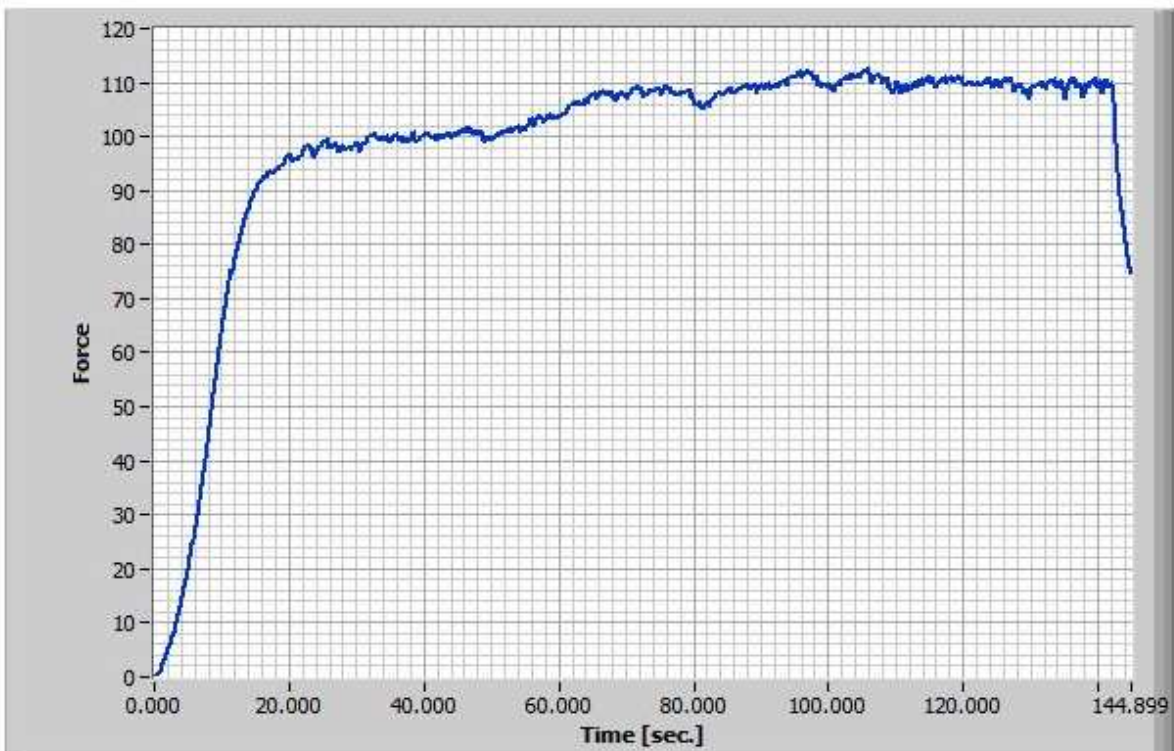
Minimum: 0.2000

Average: 98.7867

Area Under Curve: 14314.0955

Standard Deviation: 22.1873

Variance: 492.2769



3rd L2-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 140.800

Statistics

Maximum: 109.5000

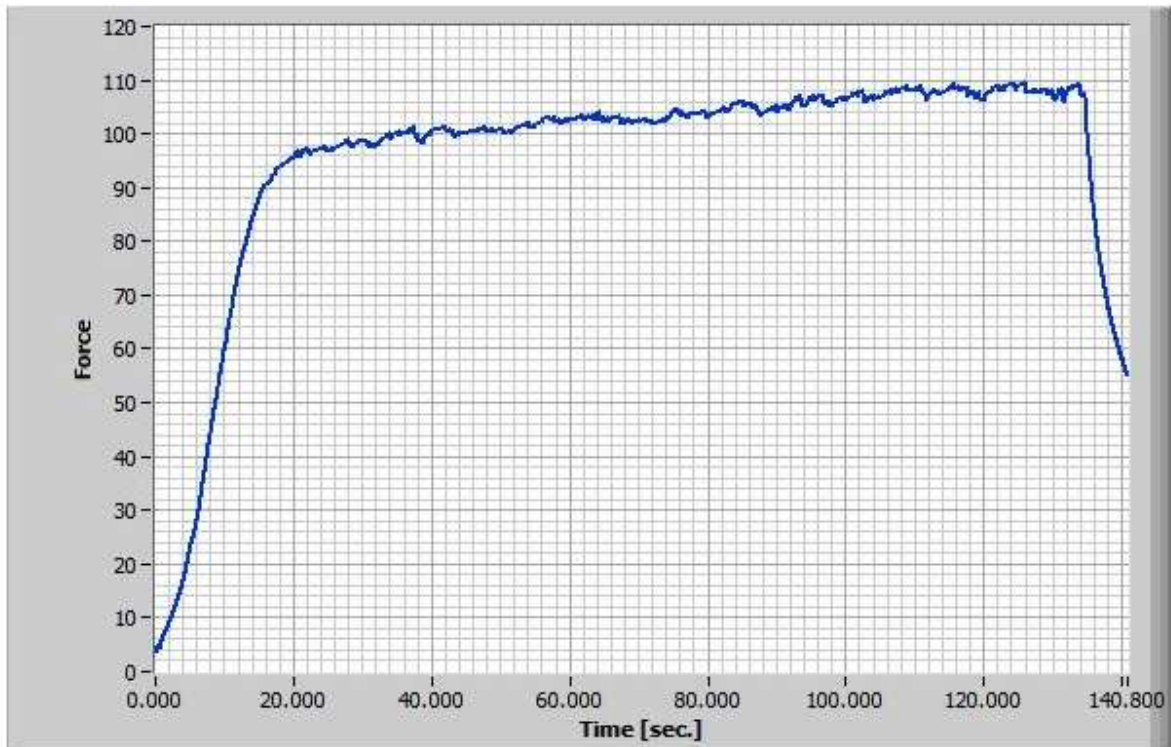
Minimum: 3.5000

Average: 95.5841

Area Under Curve: 13458.2434

Standard Deviation: 21.7120

Variance: 471.4096



3rd L2-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 153.253

Statistics

Maximum: 102.4000

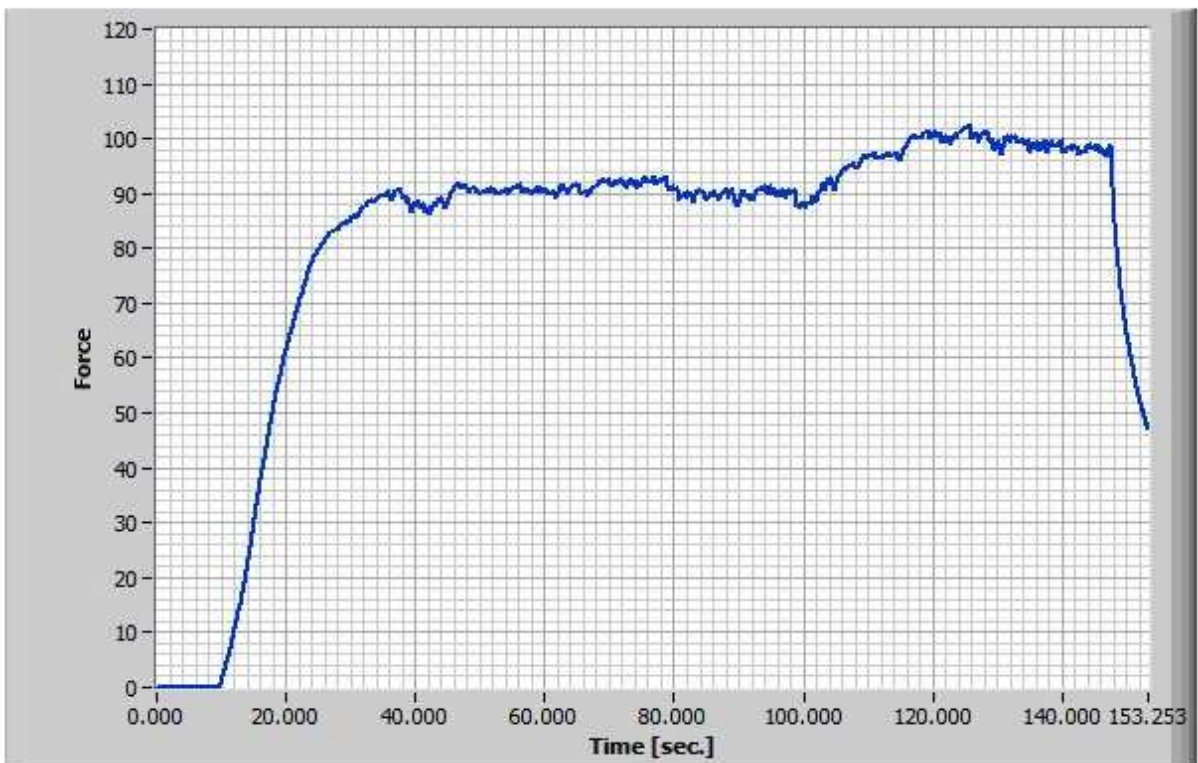
Minimum: 0.0000

Average: 80.9488

Area Under Curve: 12405.6527

Standard Deviation: 27.7159

Variance: 768.1689



3rd L3-1.log

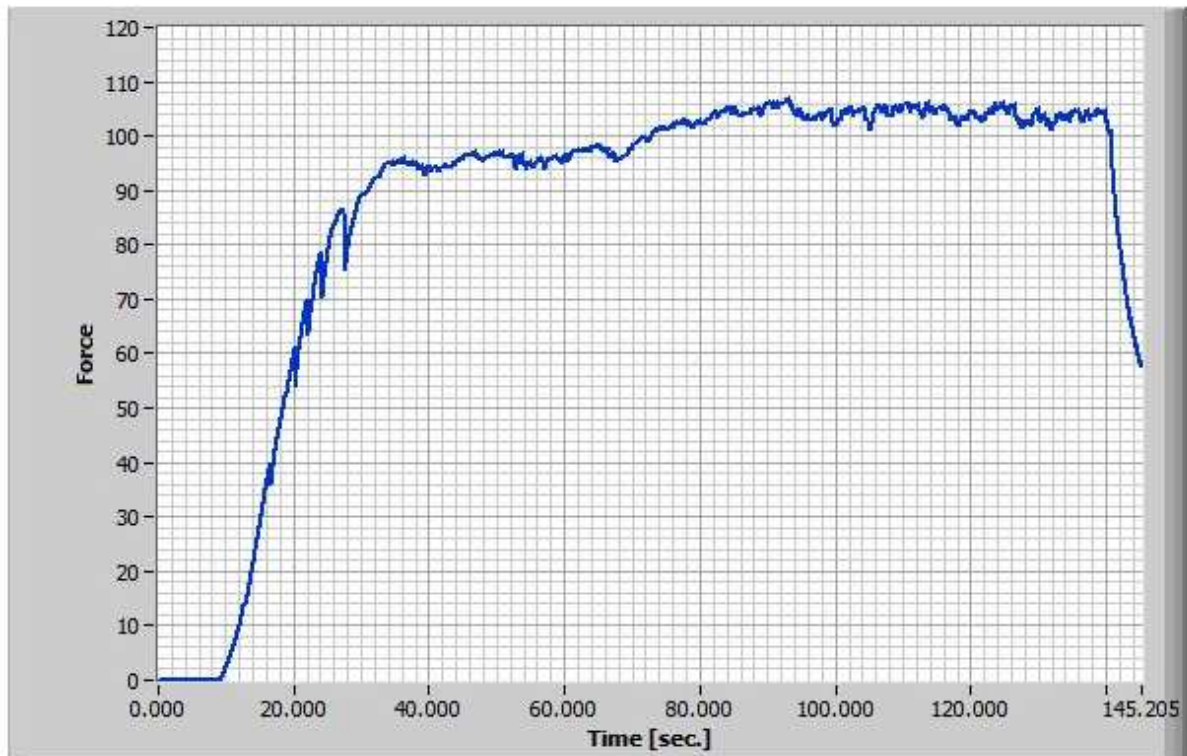
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 145.205

Statistics

Maximum: 106.9000
Minimum: 0.0000
Average: 86.3772
Area Under Curve: 12542.3957
Standard Deviation: 30.8669
Variance: 952.7645



3rd L3-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 143.350

Statistics

Maximum: 112.2000

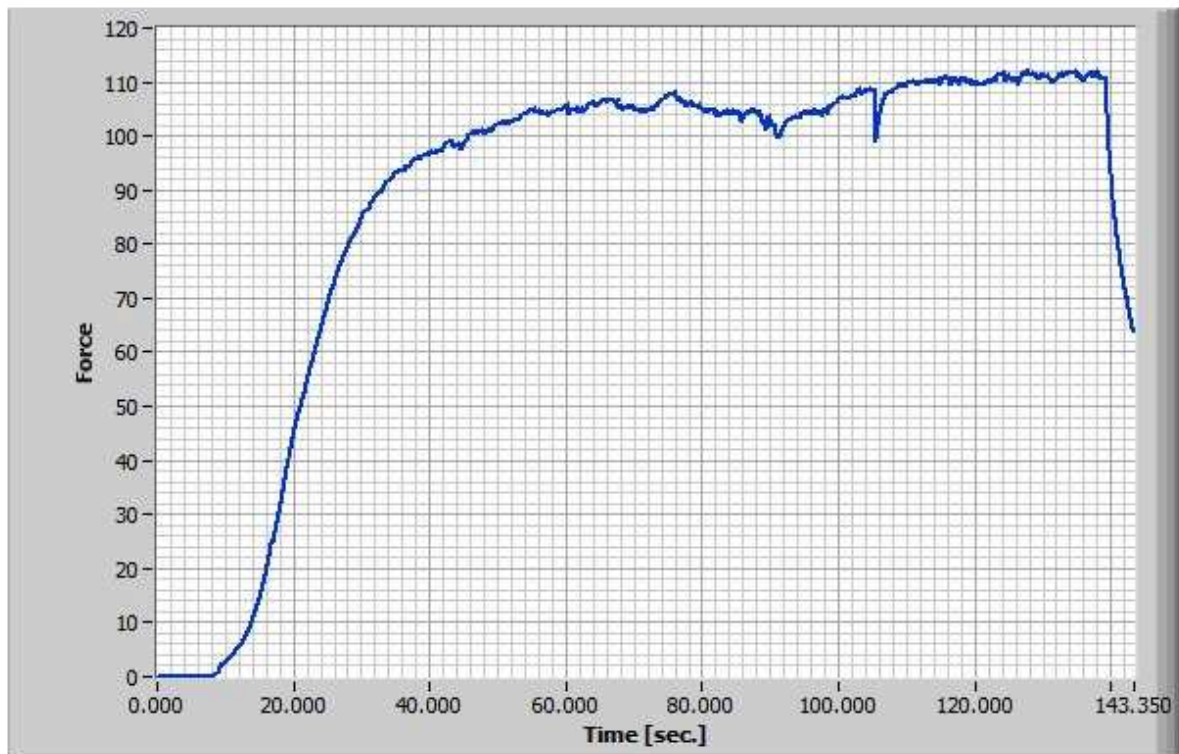
Minimum: 0.0000

Average: 88.2173

Area Under Curve: 12645.9550

Standard Deviation: 34.3055

Variance: 1176.8698



3rd L3-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 151.109

Statistics

Maximum: 110.7000

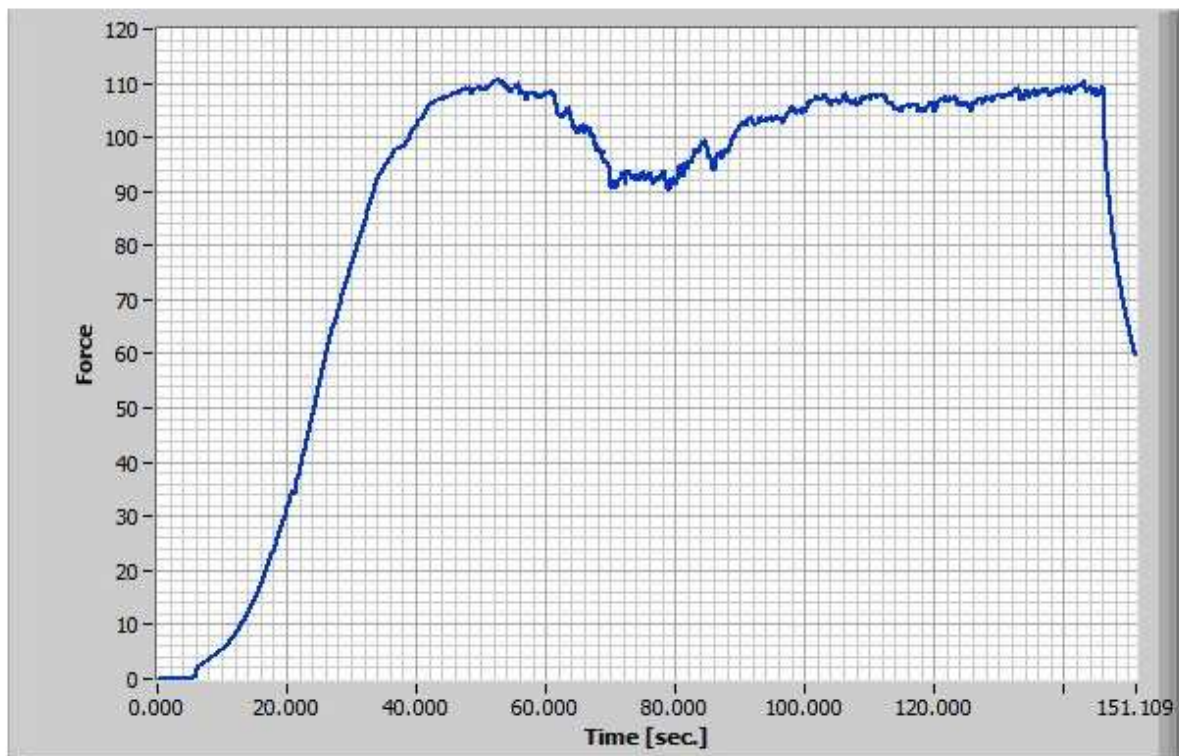
Minimum: 0.0000

Average: 86.5293

Area Under Curve: 13075.3502

Standard Deviation: 33.8714

Variance: 1147.2727



3rd L1-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.600

Statistics

Maximum: 0.0000

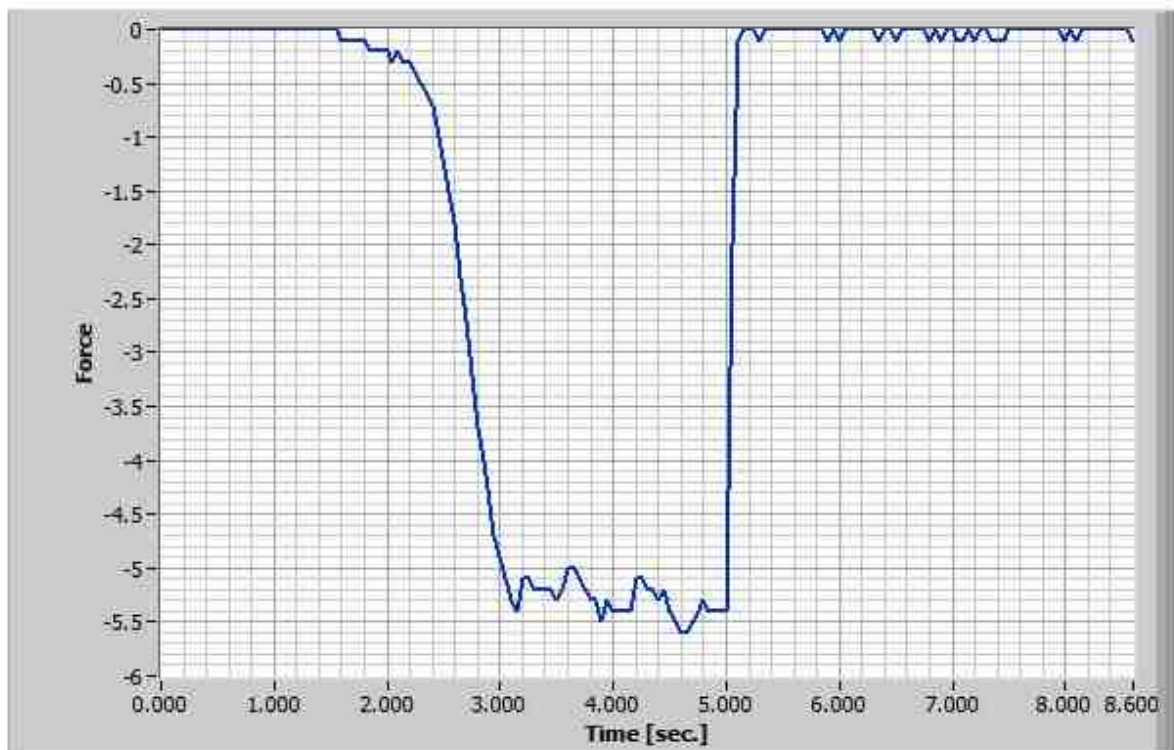
Minimum: -5.6000

Average: -1.5018

Area Under Curve: -12.9152

Standard Deviation: 2.2672

Variance: 5.1404



3rd L1-2.log

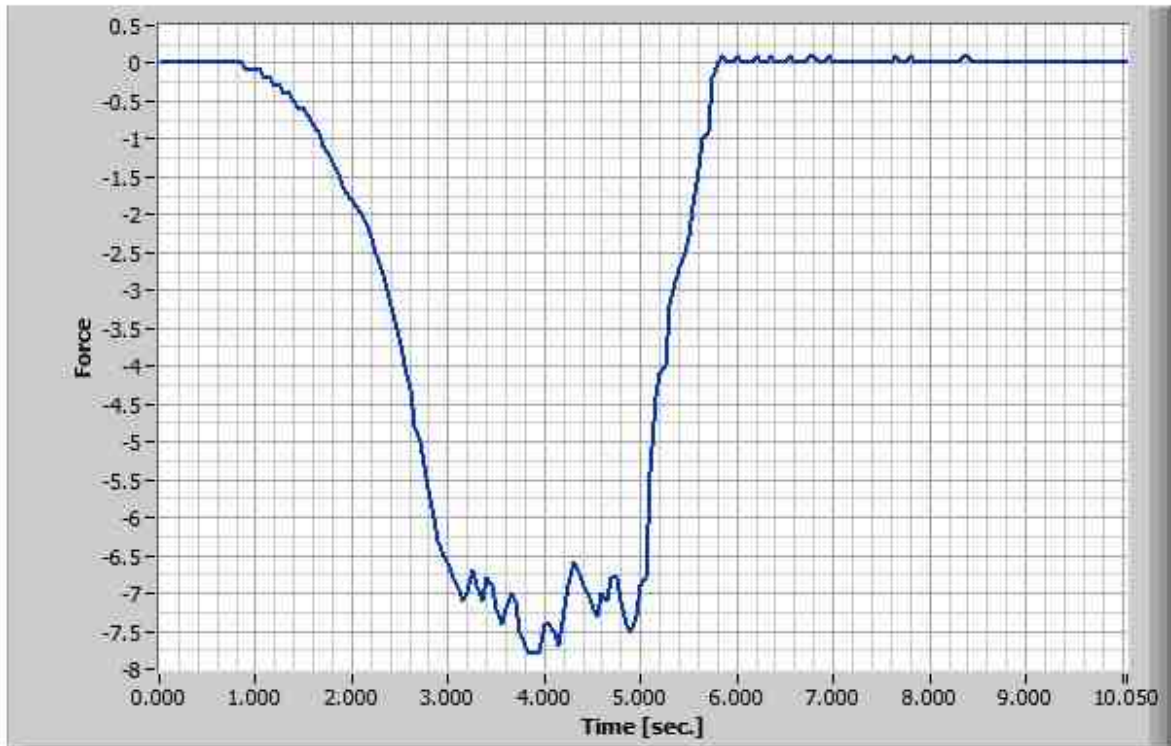
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 10.050

Statistics

Maximum: 0.1000
Minimum: -7.8000
Average: -2.1214
Area Under Curve: -21.3200
Standard Deviation: 2.9322
Variance: 8.5981



3rd L1-3.log

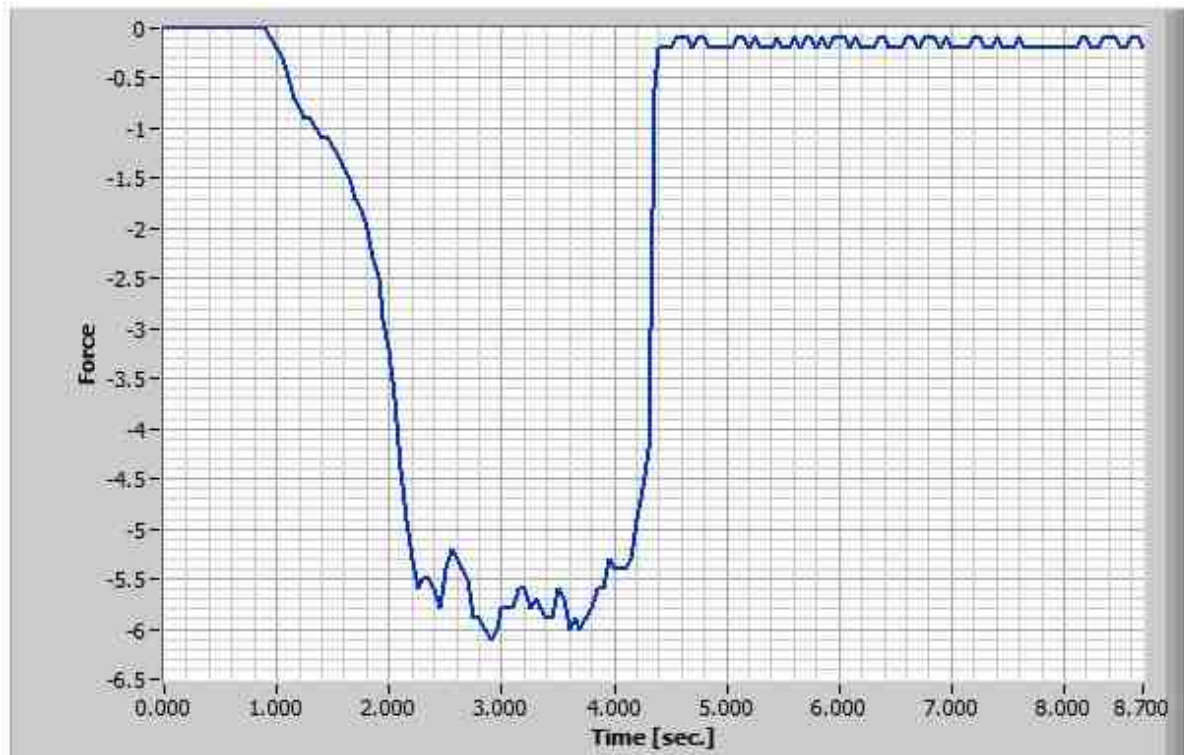
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 8.700

Statistics

Maximum: 0.0000
Minimum: -6.1000
Average: -1.7173
Area Under Curve: -14.9409
Standard Deviation: 2.3534
Variance: 5.5385



3rd L2-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.800

Statistics

Maximum: 0.0000

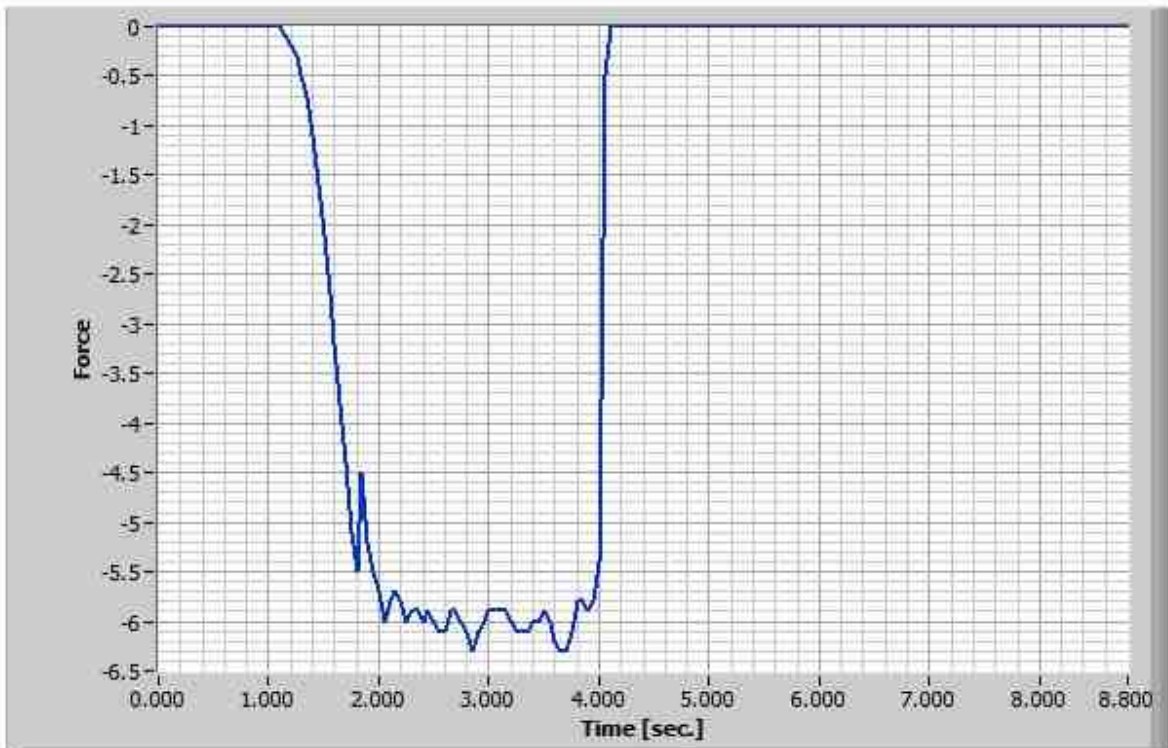
Minimum: -6.3000

Average: -1.6759

Area Under Curve: -14.7476

Standard Deviation: 2.5963

Variance: 6.7410



3rd L2-2.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 7.351

Statistics

Maximum: 0.0000

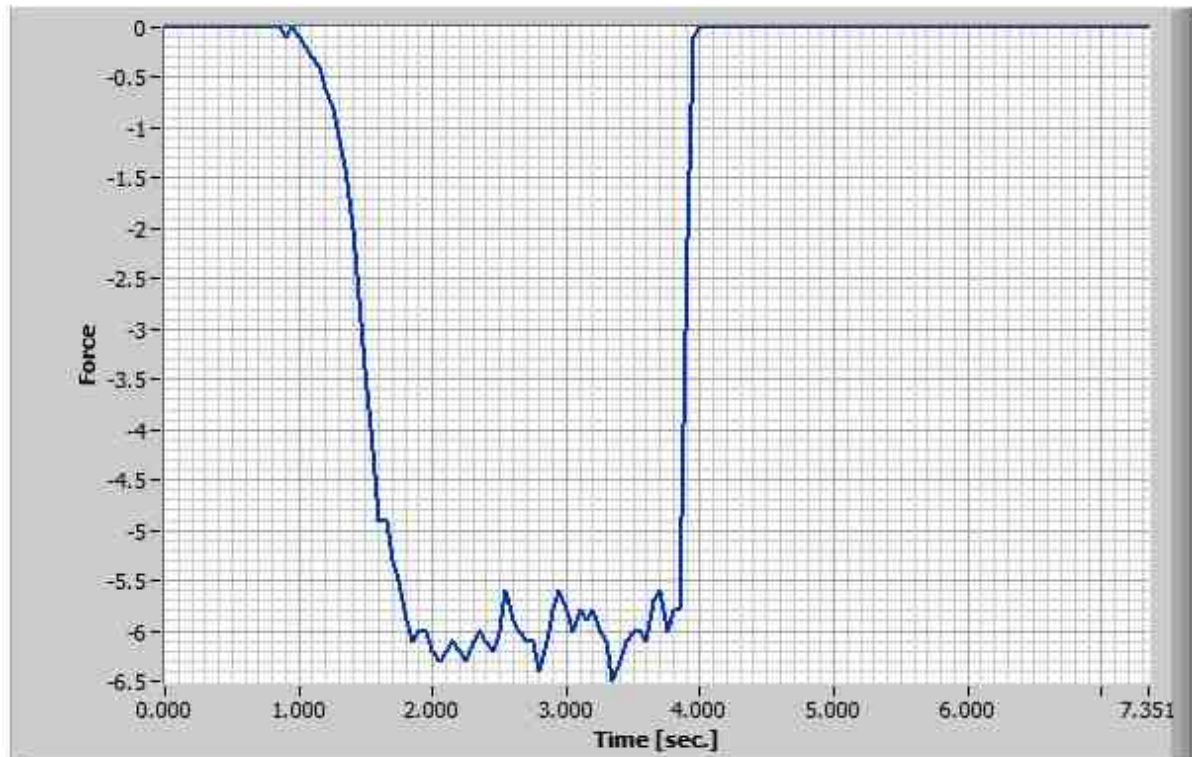
Minimum: -6.5000

Average: -1.9912

Area Under Curve: -14.6370

Standard Deviation: 2.7373

Variance: 7.4926



3rd L2-3.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 8.300

Statistics

Maximum: 0.0000

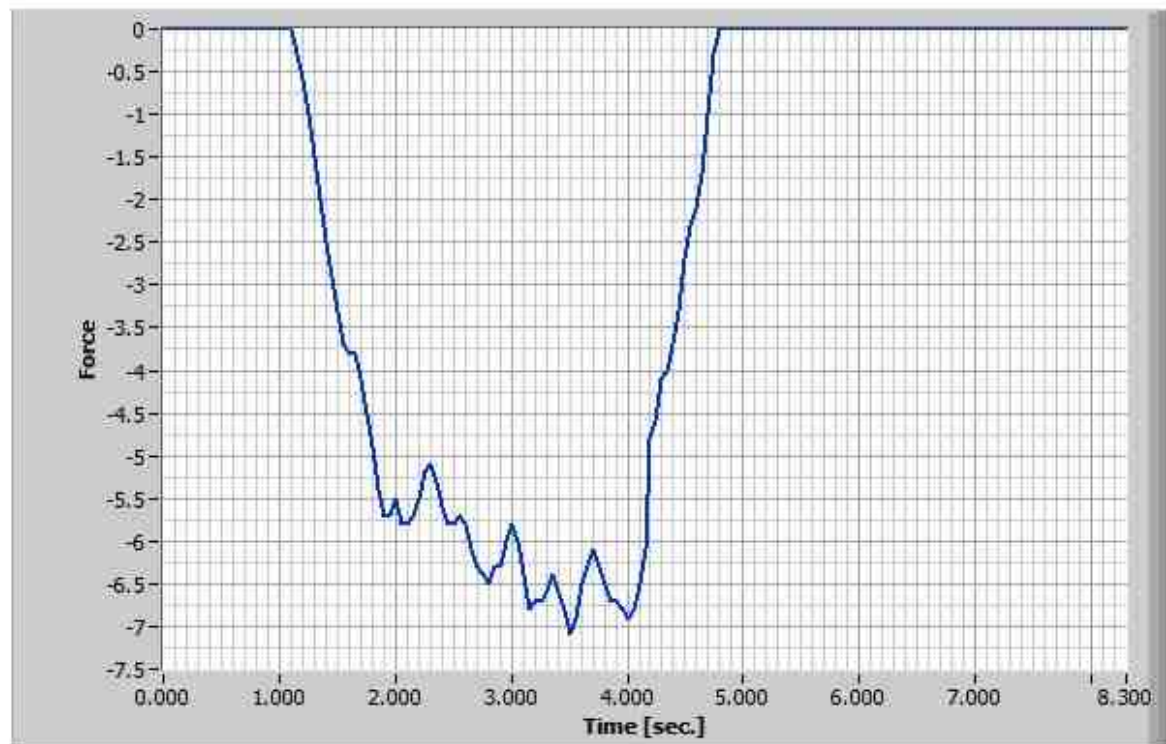
Minimum: -7.1000

Average: -2.2048

Area Under Curve: -18.3002

Standard Deviation: 2.7746

Variance: 7.6983



3rd L3-1.log

LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000

Maximum: 9.700

Statistics

Maximum: 0.0000

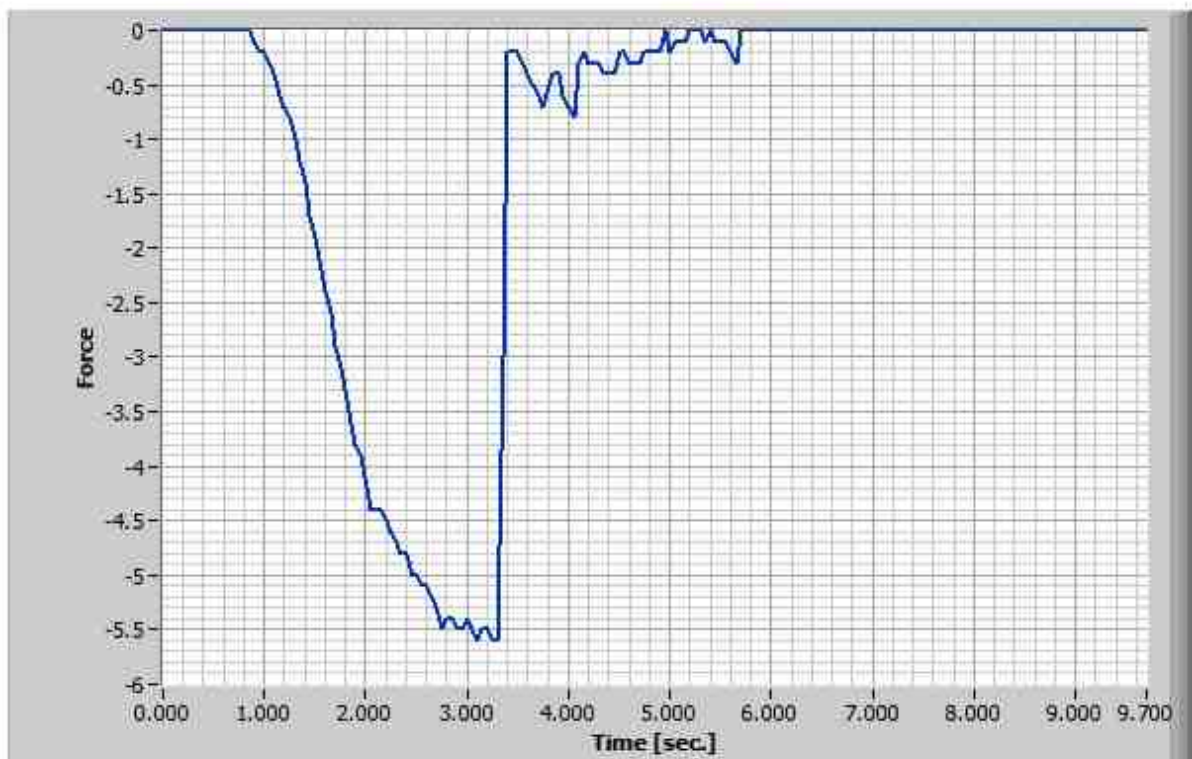
Minimum: -5.6000

Average: -0.9907

Area Under Curve: -9.6095

Standard Deviation: 1.8123

Variance: 3.2844



3rd L3-2.log

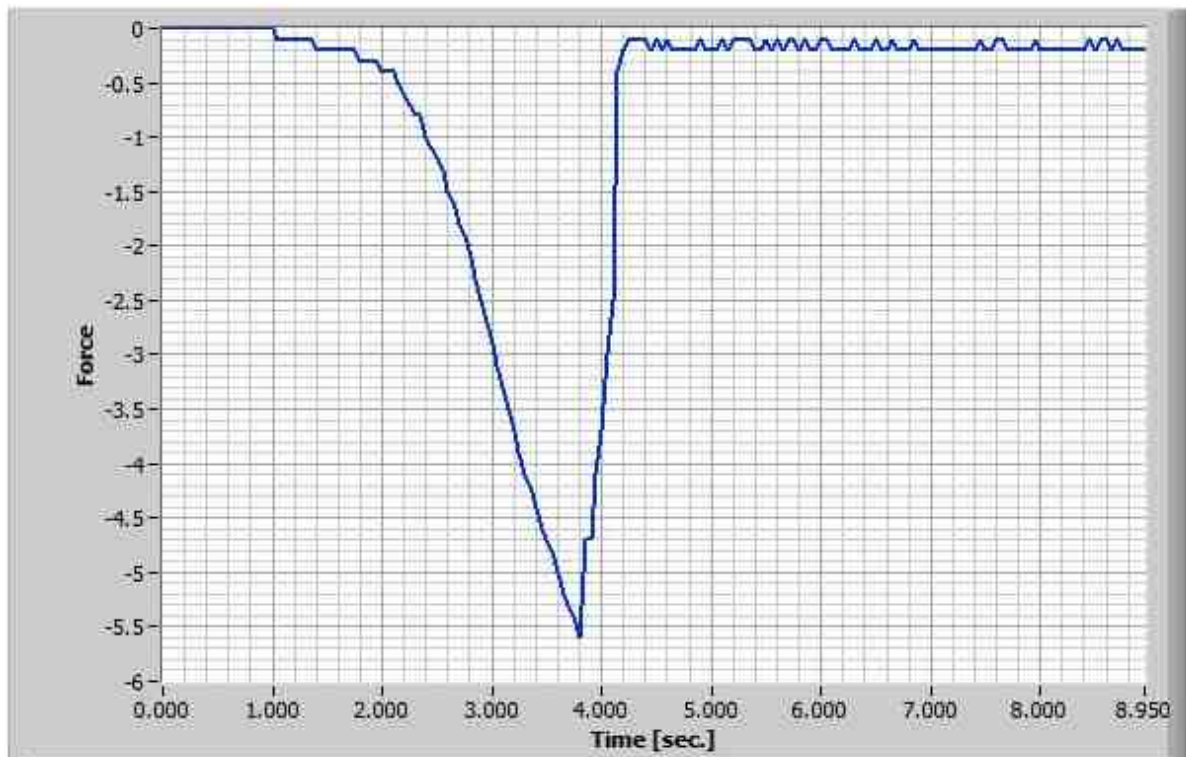
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 8.950

Statistics

Maximum: 0.0000
Minimum: -5.6000
Average: -0.7933
Area Under Curve: -7.1000
Standard Deviation: 1.4122
Variance: 1.9944



3rd L3-3.log

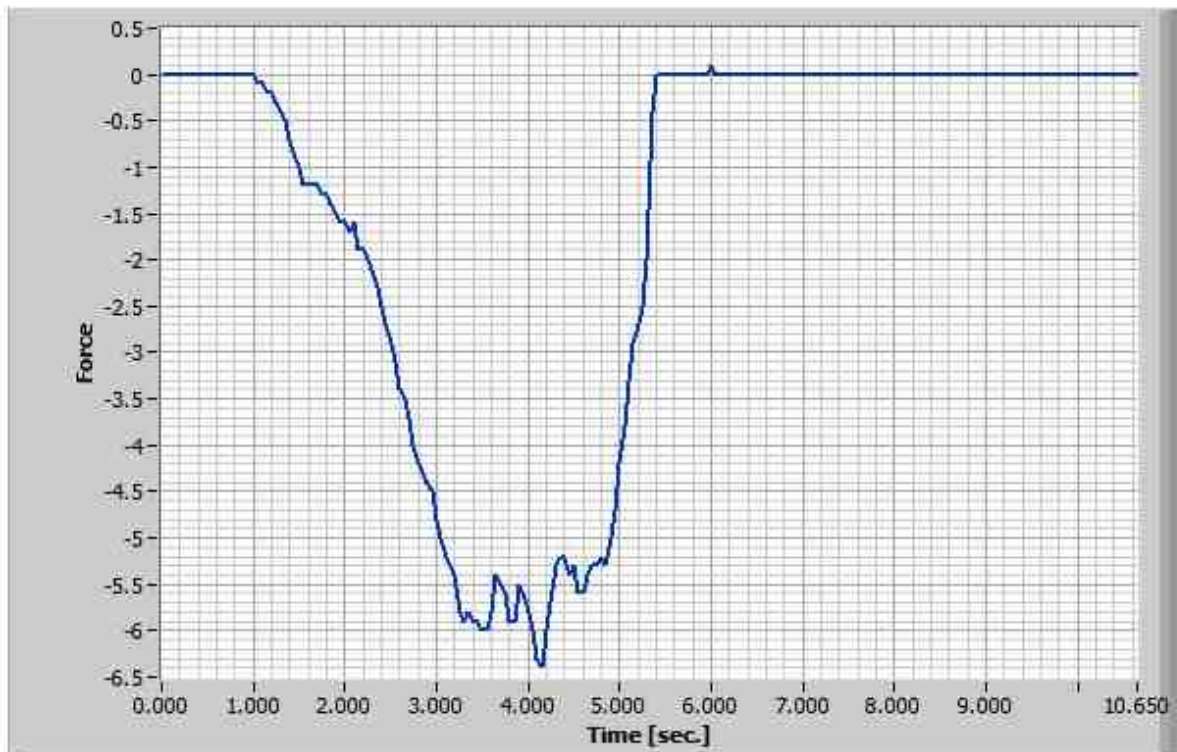
LOAD UNIT: N

X-Scale Settings (Time [sec.])

Minimum: 0.000
Maximum: 10.650

Statistics

Maximum: 0.1000
Minimum: -6.4000
Average: -1.5024
Area Under Curve: -16.0001
Standard Deviation: 2.2194
Variance: 4.9255





STERILITY TEST REPORT

Written by	Reviewed by	Approved by
7/8	/	7/8

Test Information

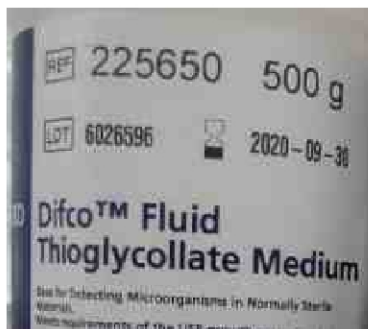
Start date	2016. 6. 23	End date	2016. 7. 7	Tester	Jeon, Eung-Jae
Test Method	according to Report 9				

Product Information

	Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Date of manufacture	2015.4.12. / 2016.5.3. / 2016.5.27
	Model	DENEJ-JC	Lot No.	FDBIM3CXX160401 / FDBIM3CXX160501 / FDBIM3CXX160502

Reagent Information

Reagent name	Fluid Thioglycollate medium	Manufacturer	BD	Lot No.	6026596
Reagent name	Tryptic soy broth	Manufacturer	BD	Lot No.	6189527



Growth Promotion Test

Fluid Thioglycollate medium	Test Strains	■ Clostridium sporogenes [ATCC11437]	The Presence of microorganisms	Presence
		■ Pseudomonas aeruginosa [ATCC9027]		Presence
		■ Staphylococcus aureus [ATCC6538]		Presence
Tryptic soy broth		■ Aspergillus brasiliensis [ATCC16404]	The Presence of microorganisms	Presence
		■ Bacillus subtilis [ATCC6633]		Presence
		■ Candida albicans [ATCC10231]		Presence

Prepare FTM (Fluid Thioglycollate Medium) and TSB (Tryptic soy broth).

As shown in the table below, the microorganisms should clearly grow when putting a small amount (less than 100c.f.u) of each strain in a medium and incubating bacteria within 3 days and fungi within 5days.

Fluid Thioglycollate Medium				Tryptic soy broth			
Control	Experiment			Control	Experiment		
Blank	Clostridium sporogenes	Pseudomonas aeruginosa	Staphylococcus aureus	Blank	Aspergillus brasiliensis	Bacillus subtilis	Candida albicans
	ATCC11437	ATCC9027	ATCC6538		ATCC16404	ATCC6633	ATCC10231
Incubation condition				Incubation condition			
30~35°C / 3days				20~25°C / 5days			



STERILITY TEST REPORT

Fluid Thioglycollate Medium					Tryptic soy broth						
Strain	Control		Experiment			Strain	Control		Experiment		
	Blank	Clostridium sporogenes	Pseudomonas aeruginosa	Staphylococcus aureus	Blank		Aspergillus brasiliensis	Bacillus subtilis	Candida albicans		
		ATCC11437	ATCC9027	ATCC6538			ATCC16404	ATCC6633	ATCC10231		
0day	(-)	(-)	(-)	(-)	0day	(-)	(-)	(-)	(-)		
1day	(-)	(-)	(-)	(-)	1day	(-)	(-)	(-)	(-)		
2days	(-)	(+)	(+)	(+)	2days	(-)	(-)	(+)	(+)		
3days	(-)	(+)	(+)	(+)	3days	(-)	(+)	(+)	(+)		
4days	/	/	/	/	4days	(-)	(+)	(+)	(+)		
5days	/	/	/	/	5days	(-)	(+)	(+)	(+)		
Result	It is conformed that each of the test organisms showed apparent growth within 3 days in the case of bacteria and within 5days in the case of fungi.										

- Prepare FTM (Fluid Thioglycollate Medium) and TSB (Tryptic soy broth).
 When incubating FTM at (30 and 35) °C and TSB at (20 and 25) °C for 14 days, microorganism should not grow.

Culture media	1 day	2 days	3 days	4 days	5 days	6 days	7 days	8 days	9 days	10 days	11 days	12 days	13 days	14 days	Result
Fluid Thioglycollate Medium	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	PASS
Tryptic soy broth	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	PASS
Result	The result of sterility of culture medium showed no growth of microorganism when the media were incubated for 14 days														

Microorganism Growth Obstruction Activity Test

Media	Test Strains	Inoculation quantity	incubation	Sample Media	Control Media	Judgement
Fluid Thioglycollate medium	S. aureus	10~100	Aerobic 30°C, 7days	G	G	No Inhibiting substance
	P. aeruginosa			G	G	No Inhibiting substance
	C. sporogenes			G	G	No Inhibiting substance
Tryptic soy broth	Bacillus subtilis	10~100	Aerobic 25°C, 7days	G	G	No Inhibiting substance
	Aspergillus brasiliensis			G	G	No Inhibiting substance
	Candida albicans			G	G	No Inhibiting substance

G : Growth N.G : No Growth



STERILITY TEST REPORT

Sterility Test_Lot #1							
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160401	1	No growth	No growth	No growth	
			2	No growth	No growth	No growth	
			3	No growth	No growth	No growth	
	Negative control			No growth	No growth	No growth	
	Tryptic soy broth	FDBIM3CXX160401	1	No growth	No growth	No growth	
			2	No growth	No growth	No growth	
			3	No growth	No growth	No growth	
	Negative control			No growth	No growth	No growth	
Sterility Test_Lot #2							
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160501	1	No growth	No growth	No growth	
			2	No growth	No growth	No growth	
			3	No growth	No growth	No growth	
	Negative control			No growth	No growth	No growth	
	Tryptic soy broth	FDBIM3CXX160501	1	No growth	No growth	No growth	
			2	No growth	No growth	No growth	
			3	No growth	No growth	No growth	
	Negative control			No growth	No growth	No growth	
Sterility Test_Lot #3							
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160502	1	No growth	No growth	No growth	
			2	No growth	No growth	No growth	
			3	No growth	No growth	No growth	
	Negative control			No growth	No growth	No growth	
	Tryptic soy broth	FDBIM3CXX160502	1	No growth	No growth	No growth	
			2	No growth	No growth	No growth	
			3	No growth	No growth	No growth	
	Negative control			No growth	No growth	No growth	



STERILITY TEST REPORT

Written by	Reviewed by	Approved by
8/3	/	8/3

Test Information

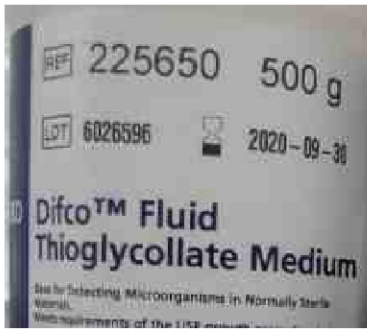
Start date	2016. 7. 19	End date	2016. 8. 2	Tester	Jeon, Eung-Jae
Test Method	according to Report 9				

Product Information

	Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Date of manufacture	2015.4.12. / 2016.5.3. / 2016.5.27
	Model	DENEB-JC	Lot No.	FDBIM3CXX160401 / FDBIM3CXX160501 / DBIM3CXX160502

Reagent Information

Reagent name	Fluid Thioglycollate medium	Manufacturer	BD	Lot No.	6026596
Reagent name	Tryptic soy broth	Manufacturer	BD	Lot No.	6189527



Growth Promotion Test

Fluid Thioglycollate medium	Test Strains	■ Clostridium sporogenes [ATCC11437]	The Presence of microorganisms	Presence
		■ Pseudomonas aeruginosa [ATCC9027]		Presence
		■ Staphylococcus aureus [ATCC6538]		Presence
Tryptic soy broth		■ Aspergillus brasiliensis [ATCC16404]	The Presence of microorganisms	Presence
		■ Bacillus subtilis [ATCC6633]		Presence
		■ Candida albicans [ATCC10231]		Presence

Prepare FTM (Fluid Thioglycollate Medium) and TSB (Tryptic soy broth).

As shown in the table below, the microorganisms should clearly grow when putting a small amount (less than 100c.f.u) of each strain in a medium and incubating bacteria within 3 days and fungi within 5days.

Fluid Thioglycollate Medium				Tryptic soy broth			
Control	Experiment			Control	Experiment		
Blank	Clostridium sporogenes	Pseudomonas aeruginosa	Staphylococcus aureus	Blank	Aspergillus brasiliensis	Bacillus subtilis	Candida albicans
	ATCC11437	ATCC9027	ATCC6538		ATCC16404	ATCC6633	ATCC10231
Incubation condition				Incubation condition			
30~35°C / 3days				20~25°C / 5days			



STERILITY TEST REPORT

Fluid Thioglycollate Medium					Tryptic soy broth				
Strain	Control		Experiment		Strain	Control		Experiment	
	Blank	Clostridium sporogenes	Pseudomonas aeruginosa	Staphylococcus aureus		Blank	Aspergillus brasiliensis	Bacillus subtilis	Candida albicans
		ATCC11437	ATCC9027	ATCC6538			ATCC16404	ATCC6633	ATCC10231
0day	(-)	(-)	(-)	(-)	0day	(-)	(-)	(-)	(-)
1day	(-)	(-)	(-)	(-)	1day	(-)	(-)	(-)	(-)
2days	(-)	(+)	(+)	(+)	2days	(-)	(-)	(+)	(+)
3days	(-)	(+)	(+)	(+)	3days	(-)	(+)	(+)	(+)
4days	/	/	/	/	4days	(-)	(+)	(+)	(+)
5days	/	/	/	/	5days	(-)	(+)	(+)	(+)
Result	It is conformed that each of the test organisms showed apparent growth within 3 days in the case of bacteria and within 5days in the case of fungi.								

- Prepare FTM (Fluid Thioglycollate Medium) and TSB (Tryptic soy broth).
 When incubating FTM at (30 and 35) °C and TSB at (20 and 25) °C for 14 days, microorganism should not grow.

Culture media	1 day	2 days	3 days	4 days	5 days	6 days	7 days	8 days	9 days	10 days	11 days	12 days	13 days	14 days	Result
Fluid Thioglycollate Medium	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	PASS
Tryptic soy broth	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	PASS
Result	The result of sterility of culture medium showed no growth of microorganism when the media were incubated for 14 days														

Microorganism Growth Obstruction Activity Test

Media	Test Strains	Inoculation quantity	incubation	Sample Media	Control Media	Judgement
Fluid Thioglycollate medium	S. aureus	10~100	Aerobic 30°C, 7days	G	G	No Inhibiting substance
	P. aeruginosa			G	G	No Inhibiting substance
	C. sporogenes			G	G	No Inhibiting substance
Tryptic soy broth	Bacillus subtilis	10~100	Aerobic 25°C, 7days	G	G	No Inhibiting substance
	Aspergillus brasiliensis			G	G	No Inhibiting substance
	Candida albicans			G	G	No Inhibiting substance

G : Growth N.G : No Growth



STERILITY TEST REPORT

Sterility Test_Lot #1								
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo	
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160401	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Trypic soy broth	FDBIM3CXX160401	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Sterility Test_Lot #2							
	Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160501	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Trypic soy broth	FDBIM3CXX160501	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Sterility Test_Lot #3							
	Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160502	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Trypic soy broth	FDBIM3CXX160502	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		



STERILITY TEST REPORT

Written by	Reviewed by	Approved by
10/6	/	10/6

Test Information

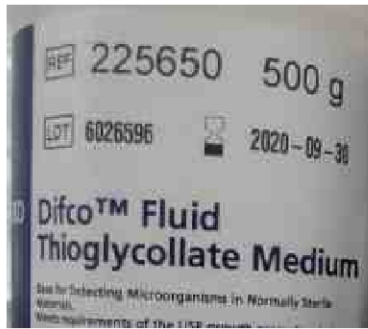
Start date	2016. 9. 21	End date	2016. 10. 5	Tester	Jeon, Eung-Jae
Test Method	according to Report 9				

Product Information

	Product name	Sterile Absorbable Hyaluronic Acid Dermal Filler	Date of manufacture	2015.4.12. / 2016.5.3. / 2016.5.27
	Model	DENEB-JC	Lot No.	FDBIM3CXX160401 / FDBIM3CXX160501 / BIM3CXX160502

Reagent Information

Reagent name	Fluid Thioglycollate medium	Manufacturer	BD	Lot No.	6026596
Reagent name	Tryptic soy broth	Manufacturer	BD	Lot No.	6189527



Growth Promotion Test

Fluid Thioglycollate medium	Test Strains	■ Clostridium sporogenes [ATCC11437]	The Presence of microorganisms	Presence
		■ Pseudomonas aeruginosa [ATCC9027]		Presence
		■ Staphylococcus aureus [ATCC6538]		Presence
Tryptic soy broth		■ Aspergillus brasiliensis [ATCC16404]	The Presence of microorganisms	Presence
		■ Bacillus subtilis [ATCC6633]		Presence
		■ Candida albicans [ATCC10231]		Presence

Prepare FTM (Fluid Thioglycollate Medium) and TSB (Tryptic soy broth).

As shown in the table below, the microorganisms should clearly grow when putting a small amount (less than 100c.f.u) of each strain in a medium and incubating bacteria within 3 days and fungi within 5days.

Fluid Thioglycollate Medium				Tryptic soy broth			
Control	Experiment			Control	Experiment		
Blank	Clostridium sporogenes	Pseudomonas aeruginosa	Staphylococcus aureus	Blank	Aspergillus brasiliensis	Bacillus subtilis	Candida albicans
	ATCC11437	ATCC9027	ATCC6538		ATCC16404	ATCC6633	ATCC10231
Incubation condition				Incubation condition			
30~35°C / 3days				20~25°C / 5days			



STERILITY TEST REPORT

Fluid Thioglycollate Medium					Tryptic soy broth				
Strain	Control	Experiment			Strain	Control	Experiment		
	Blank	Clostridium sporogenes	Pseudomonas aeruginosa	Staphylococcus aureus		Blank	Aspergillus brasiliensis	Bacillus subtilis	Candida albicans
		ATCC11437	ATCC9027	ATCC6538			ATCC16404	ATCC6633	ATCC10231
0day	(-)	(-)	(-)	(-)	0day	(-)	(-)	(-)	(-)
1day	(-)	(-)	(-)	(-)	1day	(-)	(-)	(-)	(-)
2days	(-)	(+)	(+)	(+)	2days	(-)	(-)	(+)	(+)
3days	(-)	(+)	(+)	(+)	3days	(-)	(+)	(+)	(+)
4days	/	/	/	/	4days	(-)	(+)	(+)	(+)
5days	/	/	/	/	5days	(-)	(+)	(+)	(+)
Result	It is conformed that each of the test organisms showed apparent growth within 3 days in the case of bacteria and within 5days in the case of fungi.								

- Prepare FTM (Fluid Thioglycollate Medium) and TSB (Tryptic soy broth).
 When incubating FTM at (30 and 35) °C and TSB at (20 and 25) °C for 14 days, microorganism should not grow.

Culture media	1 day	2 days	3 days	4 days	5 days	6 days	7 days	8 days	9 days	10 days	11 days	12 days	13 days	14 days	Result
Fluid Thioglycollate Medium	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	PASS
Tryptic soy broth	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	(-)	PASS
Result	The result of sterility of culture medium showed no growth of microorganism when the media were incubated for 14 days														

Microorganism Growth Obstruction Activity Test

Media	Test Strains	Inoculation quantity	incubation	Sample Media	Control Media	Judgement
Fluid Thioglycollate medium	S. aureus	10~100	Aerobic 30°C, 7days	G	G	No Inhibiting substance
	P. aeruginosa			G	G	No Inhibiting substance
	C. sporogenes			G	G	No Inhibiting substance
Tryptic soy broth	Bacillus subtilis	10~100	Aerobic 25°C, 7days	G	G	No Inhibiting substance
	Aspergillus brasiliensis			G	G	No Inhibiting substance
	Candida albicans			G	G	No Inhibiting substance

G : Growth N.G : No Growth



STERILITY TEST REPORT

Sterility Test_Lot #1								
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo	
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160401	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Tryptic soy broth	FDBIM3CXX160401	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		

Sterility Test_Lot #2								
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo	
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160501	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Tryptic soy broth	FDBIM3CXX160501	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		

Sterility Test_Lot #3								
Method	Media	Lot No.	Sample	Start date	Interim check	Final check	Incubation Photo	
Direct transfer method	Fluid Thioglycollate medium	FDBIM3CXX160502	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		
	Tryptic soy broth	FDBIM3CXX160502	1	No growth	No growth	No growth		
			2	No growth	No growth	No growth		
			3	No growth	No growth	No growth		
	Negative control			No growth	No growth	No growth		