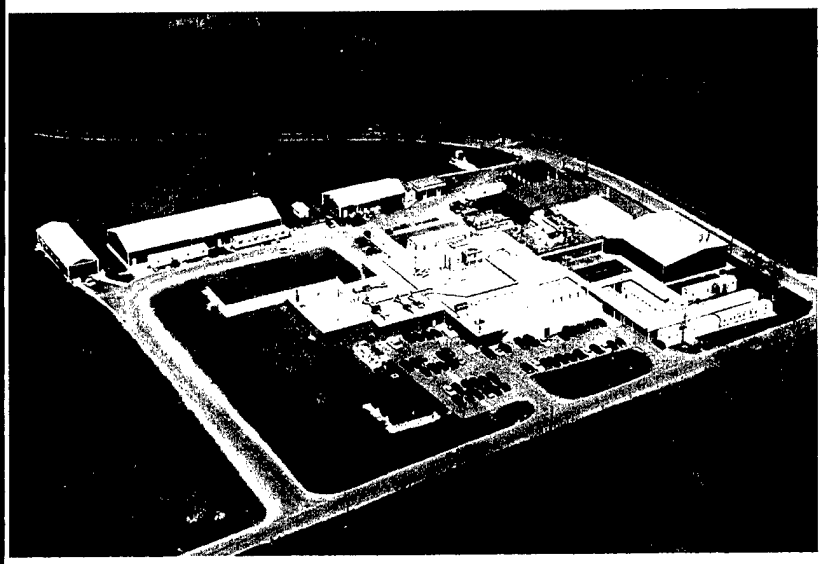
REPORT

FINAL REPORT

Task Order 0006

Technical Functional Testing of Multi-Chamber Autoinjectors (MA)



To

U.S. Army Medical Department Board

September 2000

Battelle
The Business of Innovation

FINAL REPORT

Contract No. DAMD17-99-D-0010/Task Order 0006
A Medical Research and Evaluation Facility (MREF) and Studies Supporting the Medical Chemical Defense Program

on

Technical Functional Testing of Multi-Chamber Autoinjectors (MA)

Study Number G472506B

to

U.S. Army Medical Department Board

September 2000

Tim Hayes, B.A.
Study Director

9-28-2000
Date

Larry Bullen, B.S.
Study Supervisor

9/29/2000
Date

James E. Estep, D.V.M., Ph.D.
Manager
Medical Research and Evaluation Facility

9-28-00
Date

Study performed by
BATTELLE
Product Development Group
505 King Avenue
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Table of Contents

Executive Summary

The Multi-Chambered Autoinjector (MA) is a single autoinjector containing two medicaments stored in separate chambers. The MA devices provided for this study contain only a saline solution. The device is cylindrical in shape and is approximately 18 centimeters in length (cm). The diameter is approximately 2.5 cm. The MA has a removable, gray safety cap on one end and a smaller, green cap on the needle injection end that is permanently affixed. The MA device is stored in a flexible package with notches on both ends for opening.

In-field operation of the MA device is accomplished by: (1) removing the device from the protective package, (2) removing the gray safety cap, (3) placing the green end against the thigh, and (4) pushing hard until the device activates.

The 299 MA devices tested in this study had been carried by soldiers through routine training exercises as part of the Initial Operational Test and Evaluation (IOTE) for the MA devices. Battelle conducted technical testing of the devices to determine functionality and physical condition. The laboratory testing was performed using standards established by current Good Laboratory Practices and according to MREF Protocol 176 for Study Number G472506B. The tests included measuring four parameters:

Dispensed Volume Saline (DV)
Firing Force (FF)
Time of Delivery (TD)
Needle Length (NL)

In addition to the four measurements, the condition of the protective package and of the MA was examined and recorded.

The volume of solution dispensed was calculated by the change in weight of the MA from before firing to after firing. Weights were measured using a digital scale. The firing force was recorded on a strip chart recorder as the output of a Linear Variable Displaceable Transducer (LVDT) that measured the displacement of a spring scale applying force to the MA. A through beam laser sensor was used to detect the stream of solution coming from the needle and a digital timer was used to measure the time of delivery based on the laser sensor output. The length of the needle was measured using a digital indicator. The testing procedure consisted of examining and recording the condition of the protective wrapper, examining and recording the condition of the MA, weighing the MA, placing the MA on the test stand, firing the MA and recording test results and weighing the MA again.

The condition of the protective wrappers that the MA devices were packed in varied from good to severely delaminated, punctured or not sealed. The majority of the wrappers, 295 out of the 299, were in the A, B, and C categories indicating some level of damage. There was no observed damage to any of the MA devices. All of the 299 MA devices that were tested by Battelle fired successfully and within specification for

the four measured parameters.[1] The statistical evaluation of the data (see Appendix F) projects that the number of MAs from this lot, after being subjected to the training exercises, that would perform out of specification would be less than 1 in 1,000.

[1] Data for one parameter for each of three MA devices was unavailable due to instrumentation or operator error. There was no indication that the three devices affected were not typical of the total sample.

Quality Assurance Statement

Study Number: G472506B

This study was inspected by the Quality Assurance Unit and reports were submitted to the Study Director and management as follows:

Phase Inspected	*Inspection Date*	*Date Reported To Study Director*	*Date of Report to Management*
Draft Protocol Review	05/02/2000	05/02/2000	05/04/2000
System set up and autoinjector testing	05/10/2000	05/11/2000	05/16/2000
Protocol Review	05/10/2000	05/11/2000	05/16/2000
Raw data sheets, charts and spreadsheets	05/22/2000	05/22/2000	06/02/2000
Draft Final Report	07/12/2000	07/12/2000	09/28/2000
Final Report	09/28/2000	09/28/2000	09/28/2000

Quality Assurance Unit Date

GLP Compliance Statement

Procedures in this study were performed in compliance with the Food and Drug Administration's Good Laboratory Practice regulations (21 CFR Part 58). The study was conducted according to the study protocol, and Battelle's standard operating procedures and methods. No deviations from the protocol, standard operating procedures or methods occurred. The data presented accurately reflect the results of the study.

_____ _____

Timothy L. Hayes, B.A. Date
Study Director

Introduction

The Multi-Chambered Autoinjector (MA) is a single autoinjector containing two medicaments stored in separate chambers. The MA devices provided for this study contained only a saline solution (no test or control article was used in this study). The device is cylindrical in shape and is approximately 18 centimeters in length (cm). The diameter is approximately 2.5 cm. The MA has a removable, gray safety cap on one end and a smaller, green cap on the injection end that is permanently affixed. The MA device is stored in a flexible package with notches on both ends for opening. (Appendix A - Photo 1)

In-field operation of the MA device is accomplished by: (1) removing the device from the protective package, (2) removing the gray safety cap, (3) placing the green end against the thigh, and (4) pushing hard until the device activates.

The USAMEDDBD designed an Initial Operational Test and Evaluation (IOTE) for the MA devices. The IOTE called for the MA devices to be issued to representative soldiers from Armor, Infantry, Special Operations, and Airborne units to carry during field training exercises over a 21-30 day period. The IOTE objectives are to collect data to determine:

A. The durability and functionality of the MA devices when carried by soldiers during tactical maneuvers.

B. The adequacy of training and evaluating the soldiers' ability to interpret operating instructions printed on the device.

C. The soldiers' ability to distinguish between the MA device and a similar device that is also carried by the soldiers.

Prior to the study conducted by Battelle, soldiers carried the MA devices through routine training exercises. After the MA devices were carried in the field for 21 to 30 days, 299 devices were forwarded to Battelle for functionality testing. Battelle was directed to evaluate point A of the IOTE objectives--the functionality of the devices after being carried during tactical maneuvers.

Battelle conducted technical testing of the devices to determine functionality and physical condition. The laboratory testing was performed using standards established by current Good Laboratory Practices (cGLP) and according to MREF Protocol 176 (Appendix B).

Testing Procedure

Each autoinjector was tested in accordance with Method No. 31/Chemistry: Method for Functionality Testing of Multi-Chambered Autoinjectors (Appendix C). Method 31, and others that it references, provide detailed information on the equipment used, setup, and calibration of that equipment. It also contains step by step instructions for performing the tests on the autoinjectors. In brief that procedure is as follows:

1. Record the serial number of the autoinjector on the Data Sheet.

2. Examine protective package and record observations of damage on the Data Sheet.

3. Remove autoinjector from the protective package and record observations of damage on the Data Sheet.

4. Remove the gray safety cap and discard it.

5. Place the autoinjector on the digital scale and record Initial Weight on the Data Sheet.

6. Place the autoinjector on the support stand on the Chatillon tester, reset the timer and start the strip chart recorder.

7. Execute the test.

8. Record test results. Record the Firing Force (FF) from the chart recorder and Time of Delivery (TD) from the timer on the Data Sheet.

9. Record serial number and FF directly on strip chart.

10. Remove the autoinjector from the test stand.

11. Insert the needle into the needle length adapter on the digital indicator and record the Needle Length (NL) on the Data Sheet.

12. Place the autoinjector on the digital scale and record the Final Weight on the Data Sheet.

13. Place the autoinjector in a suitable disposal container.

The equipment used included the following:

- Chatillon TCD-200 Tension/Compression Tester – used to provide the programmable motion and support structure for firing the MA.
- Autoinjector support stand – a fabricated stand mounted to the base of the Chatillon Tester to support the MA, provide mounting for the laser sensor and provide clearance for a collection vessel for the saline solution.
- Spring scale head adapter – fabricated clamp adapter which attaches to the moving head of the Chatillon Tester to hold the spring scale and the LVDT.
- Chatillon spring scale – used to apply increasing force to the MA as the Chatillon Tester feeds downward at a constant velocity.
- Sensotec +/- 2 inch DC-DC LVDT – this is mounted in the spring scale head adapter parallel to the spring scale and is coupled to the spring scale. It provides an analog DC signal proportional to the deflection of the spring scale which is fed into the strip chart recorder.
- DC power supply – provides power for the LVDT.
- Starrett Digital Indicator and needle length adapter – used to measure the extended length of the MA needle.
- Graphtec SR6312 Chart Recorder – used to record the output of the LVDT. When properly calibrated, one major unit on the strip chart corresponds to 1 pound of force being applied to the MA.
- Keyence LX2-V10W Laser Sensor – used to detect the stream of saline solution coming from the needle of the MA.
- Fluke 1953A Counter Timer – measures the duration of the signal from the laser sensor.
- Wavetek 442 Dual Hi/Lo Filter – used to filter out background noise in the signal from the laser sensor.
- Digital Oscilloscope – used to confirm the time measurement captured by the counter/timer.
- Digital Function Generator – used for calibration of the counter/timer.
- Digital scale – used to measure before and after weights of the MA to calculate volume delivered.

- Chatillon digital force gage – used to calibrate the strip chart recorder.
- Weight set – used for daily calibration check of the digital scale.

Photo 2 in Appendix A shows the test setup used to test the MAs. On the left side of the photo, there are three instruments stacked together. The instrument on the top is the power supply and controller for the laser sensor. In the middle is the timer/counter and at the bottom is the dual hi/lo filter. Of these three, the counter/timer is the only one that provides recorded data, that being the delivery time. Immediately to the right of these three is the strip chart recorder which records the firing force. The tall device to the right of center is the Chatillon Tension/Compression Tester. To the right of the Chatillon is the digital scale that is used to measure Initial and Final weights. Finally, to the right and forward of the scale is the digital indicator.

Photo 3 in Appendix A shows an MA loaded on the test stand. The two devices mounted to the right and left, and immediately below the autoinjector support stand, are the laser source and detector that make up the laser sensor.

Photo 4 in Appendix A shows a typical trace from the strip chart recorder. The strip chart records the output of the LVDT, which measures the displacement of the spring scale. As the spring scale advances, it applies an increasing force to the MA. The force increases linearly with time until the point where the device fires. At this time, the displacement of the spring scale increases very rapidly as the spring within the autoinjector is released. The Firing Force is read from the strip chart at the point of transition from the steadily increasing force to the nearly vertical increase in force. The strip chart recorder is calibrated such that one major unit on the chart corresponds to 1 pound. The shape of the trace after the MA fires has no relevance to the test.

The volume of saline delivered (Dispensed Volume Saline--DV) by the MA is calculated by subtracting the Final Weight from the Initial Weight and dividing by the Specific Gravity of the saline solution. The Initial and Final Weights are read directly from the digital scale and recorded on the data sheet. The calculation of the Delivered Volume (DV) is performed in an Excel spreadsheet located in Appendix E.

The Time of Delivery (TD) is read directly from the timer/counter and recorded on the data sheet. The timer/counter monitors the output from the laser sensor. The output of the laser sensor is proportional to the fraction of the laser beam that is unobstructed. When the MA fires, the stream of saline solution passes through the laser beam and obstructs some part of the beam and the output from the sensor decreases. The timer/counter begins timing when the output from the laser sensor drops below a preset trigger level and stops timing when the output rises above the trigger level.

The Needle Length (NL) is read directly from the digital indicator. The indicator is set to hold and display the maximum deflection. The needle on the MA is inserted into the needle length adapter on the indicator until the end of the MA is against the end of the

adapter. The indictor holds the display of the maximum reading until it is reset. The value is recorded on the data sheet.

The condition of each MA package is observed and recorded prior to opening the package. When the package is opened, the condition of the MA is again observed and recorded. Prior to the start of the testing, the condition of the MA packages was assessed and determined to fall into four groups:

A – End of package is open and has been taped closed to prevent the device from falling out of the package (Appendix A - Photos 5, 6).

B – Clear outside layer has peeled away from the brown inside layer of the package. Condition ranges from moderate to severe (Appendix A -Photos 7, 8).

C – Package is punctured exposing the device (Appendix A - Photos 9, 10).

D – In relatively good condition, no significant package damage (Appendix A - Photos 11, 12).

Because it was not possible to preview the condition of the MAs inside the packages, two categories were established to describe the device conditions: (1) the letter E is designated for no apparent damage, and (2) the letter F is designated for damage observed. These conditions are recorded in the comments column on the Data Sheets (Appendix D).

Development Units

Prior to testing these autoinjectors, Battelle received 211 autoinjectors for development and setup purposes. Details about the development phase are found in Appendix G.

Receipt of Test Units

Battelle received a total of 299 autoinjectors filled with a saline solution for final testing from the USAMEDDBD. Included with this shipment was an inventory table listing the serial numbers recorded on each unit. During Battelle's receiving and inspection process, it was determined that the inventory table and the actual number of serialized units received were not in agreement. Battelle notified the USAMEDDBD with a detailed description of these discrepancies. The USAMEDDBD, subsequently, reissued a corrected inventory table. Correspondence related to these corrections is attached to the Inspection/Test Record in the G472506B study file under "Customer Supplied Products/Receiving and Inspection."

The shipping box and its contents were found to be in good condition upon arrival at Battelle. No significant damage was found as a result of shipping, packing, or handling. Photographs of the box and its contents are attached to the "Inspection/Test Record" in the G472506B study file under "Customer Supplied Products/Receiving and Inspection."

Results

Appendix F contains a statistical analysis of the results of this study. In short, all of the 299 MAs fired properly during the test and all were within the specified limits on all four of the measured parameters.[2] Not only were the test results within the specified limits, but a review of Figures 1- 4 of Appendix F reveals that the results are grouped and well within the limits. A comparison of the test data from the 299 MAs included in this study with the lot release data from the manufacturer indicates no significant change in the Needle Length, Dispense Time or Dispensed Volume (Table 1). The average Firing Force data from this study is somewhat lower but nearer the middle of the permissible range compared to the lot release data. Based on these results, there is no indication that any of the tested MAs suffered adversely from being carried by soldiers during the training exercises.

Table 1: Study Test Results

			Study Test Results			
Attribute	**Specification**	**Lot Release**	**Minimum**	**Mean**	**Maximum**	**Standard Deviation**
NL—Needle Length (mm)	18-23	20	18.94	19.93	20.48	0.262
TD—Time of Delivery (sec)	Not More Than 7	2.7	2.56	2.64	4.72	0.313
FF—Firing Force (lbs)	2.0 –8.0	6.4	3.8	5.7	7.0	0.538
DV—Dispensed Volume Saline (ml)	2.43 – 2.97	2.74	2.60	2.74	2.89	0.049

While the quantitative results indicated no damage to the MAs due to being carried through training exercises, the packaging did suffer significant damage to most of the units. As described earlier, the packages were classified into four groups. Groups A, B and C all exhibited significant damage to the package. This damage in many cases included the MA being exposed to outside contamination. Table 2 summarizes the observations of the package conditions.

[2] Data for one parameter for each of three MA devices was unavailable due to instrumentation or operator error. There was no indication that the three devices affected were not typical of the total sample.

Table 2: Package Conditions

Group	Description	Number
A	End of package has been opened and then taped closed to prevent device from falling out of the package.	51
B	Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe.	237
C	Package is punctured exposing device.	7
D	In relatively good condition, no significant package damage.	4

Location of Records

Records pertaining to the conduct of this study, the original data, and the original final report will be archived at Battelle.

Meridian Medical Technologies provided a total of 211 devices to be used for set up purposes. Of those 211, Battelle used and then destroyed 109 after the setup and returned 102 to Meridian. The U.S. Army provided a total of 299 devices for testing, and all 299 of these devices were tested and then destroyed at Battelle. Battelle does not have any MA devices in its possession.

Appendix A. Photographs

Photo 1. Multi-Chambered Autoinjector with Package

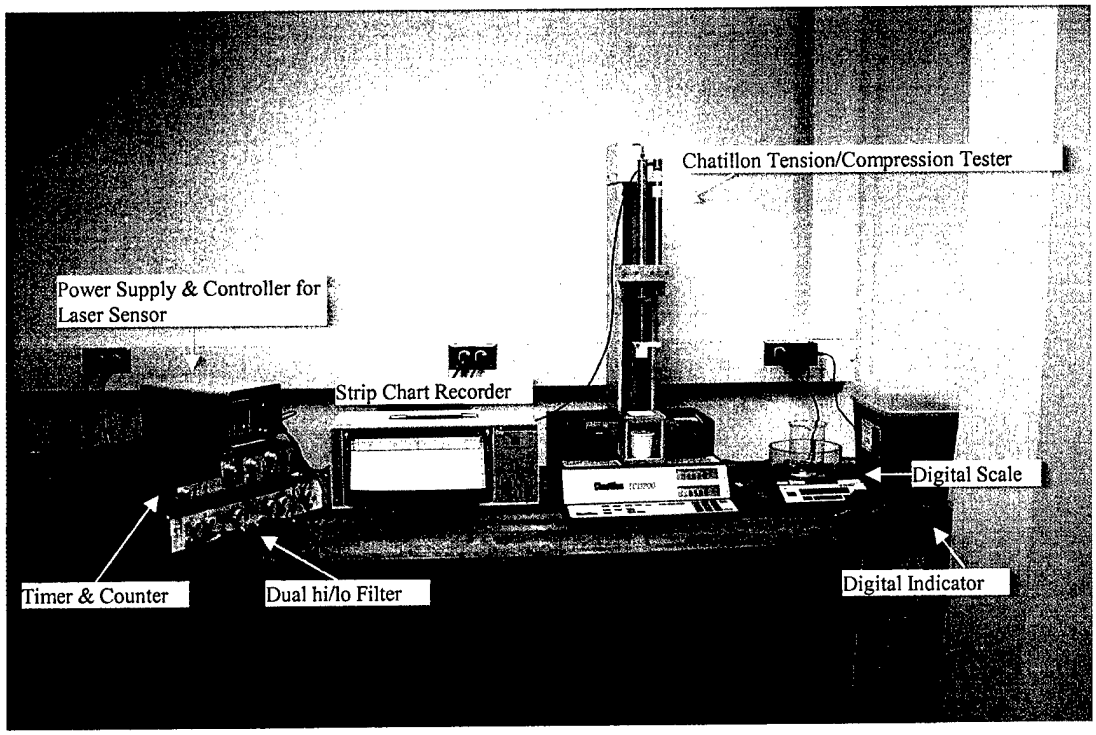

Photo 2. Test Set Up Used for Testing MAs

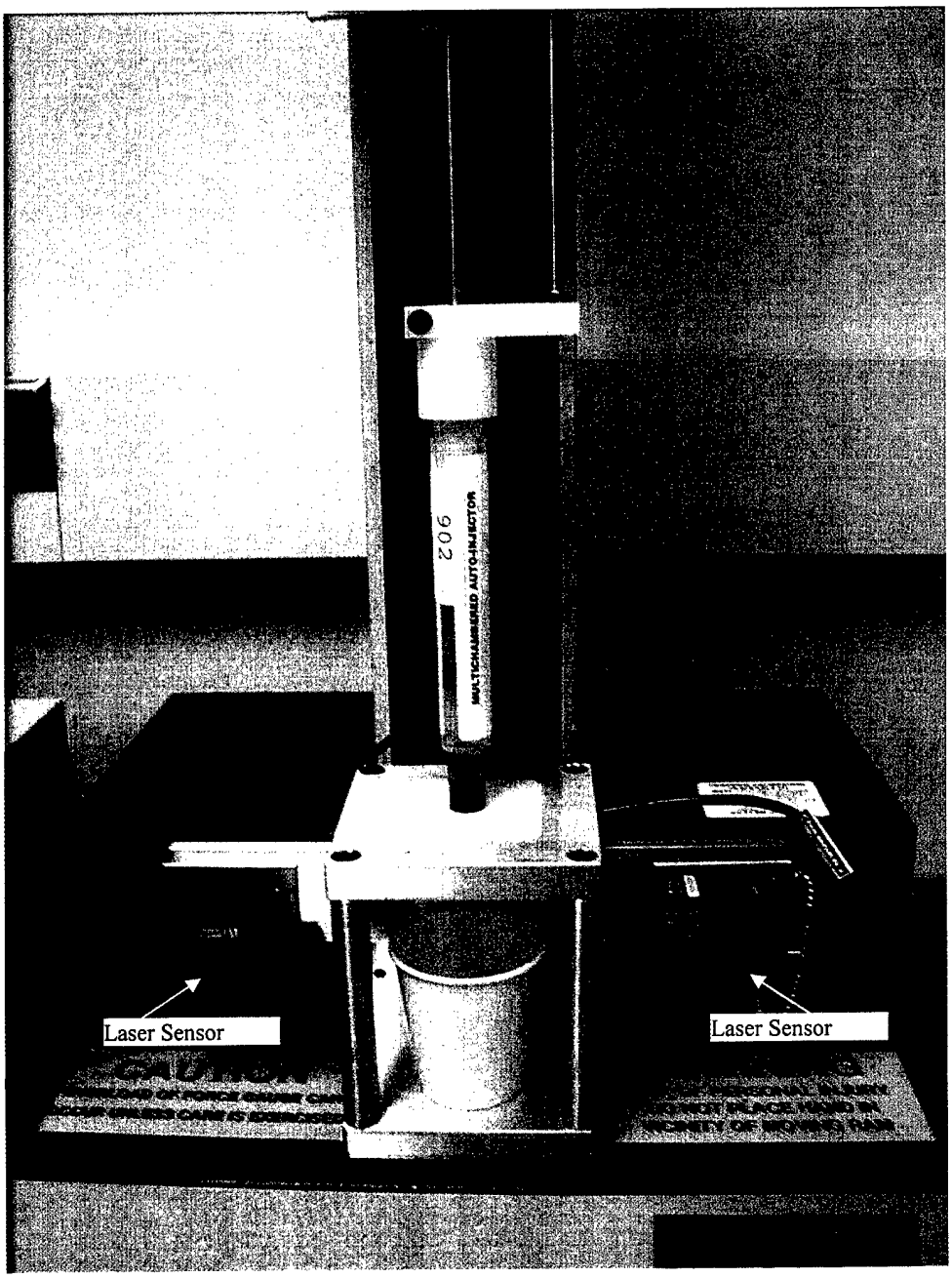

Photo 3. MA Device Loaded on Test Stand

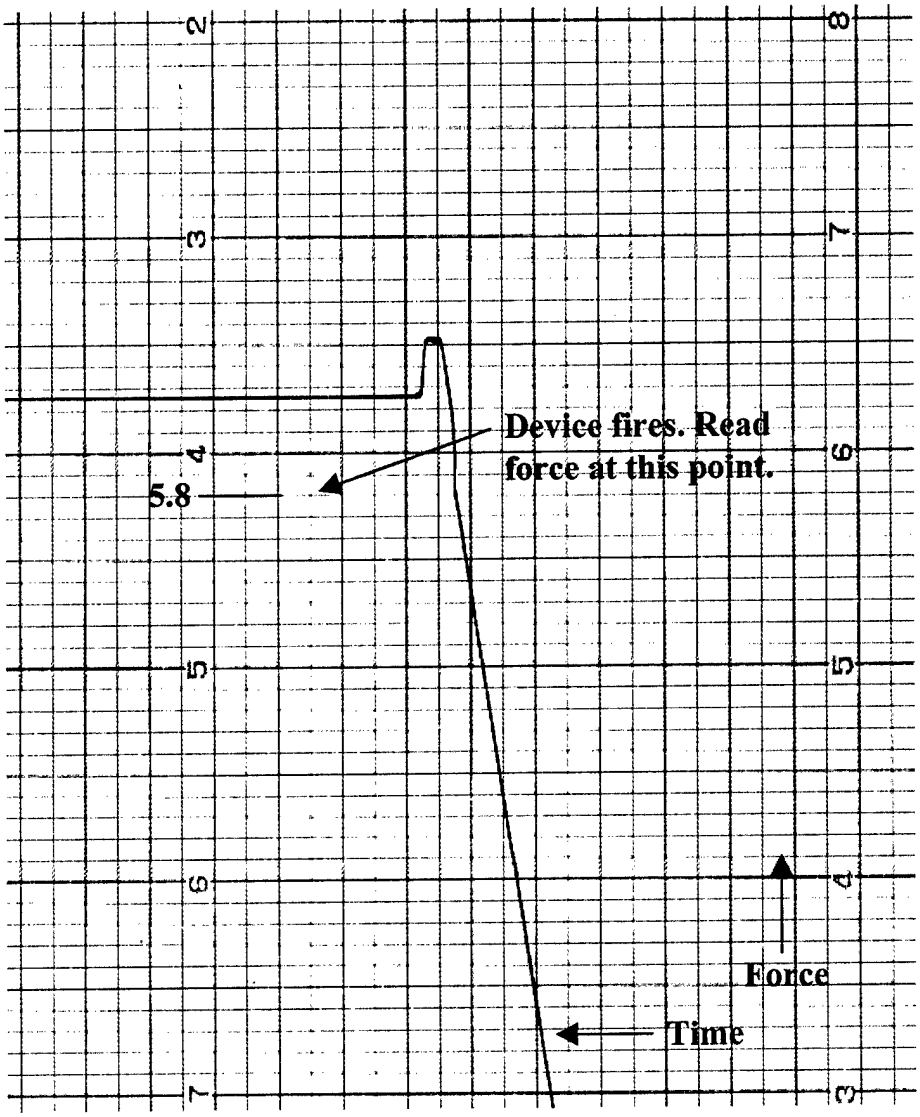

Photo 4. Typical Trace From Strip Chart Recorder

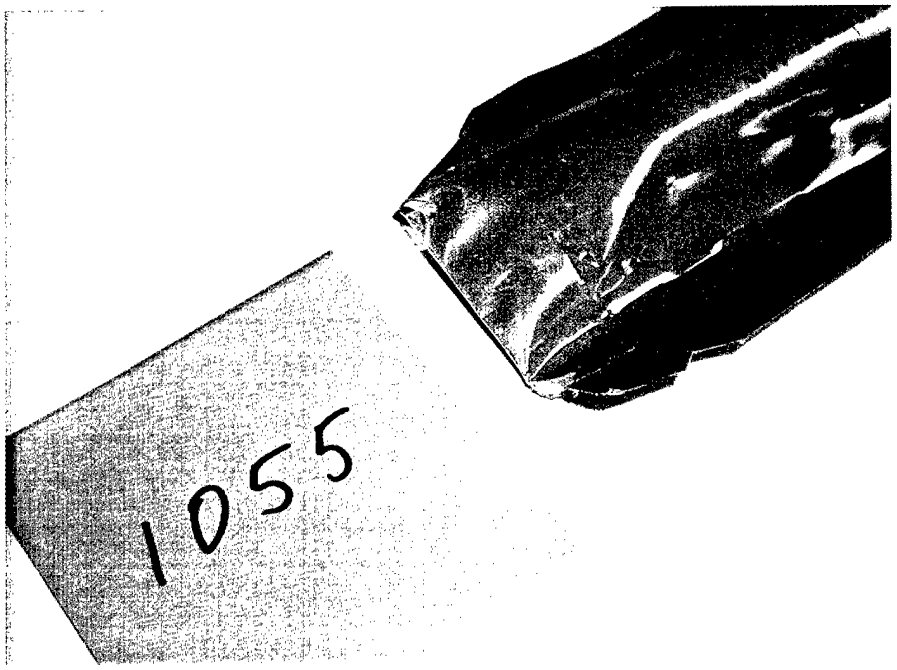

Photo 5. Group A--End of package has been opened and then taped closed to prevent device from falling out of package

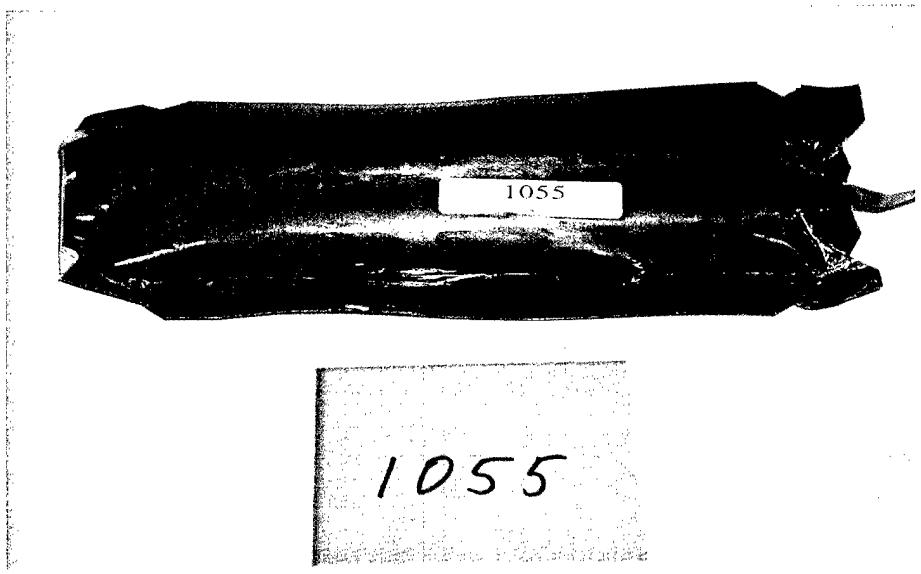

Photo 6. Group A--End of package has been opened and then taped closed to prevent device from falling out of package

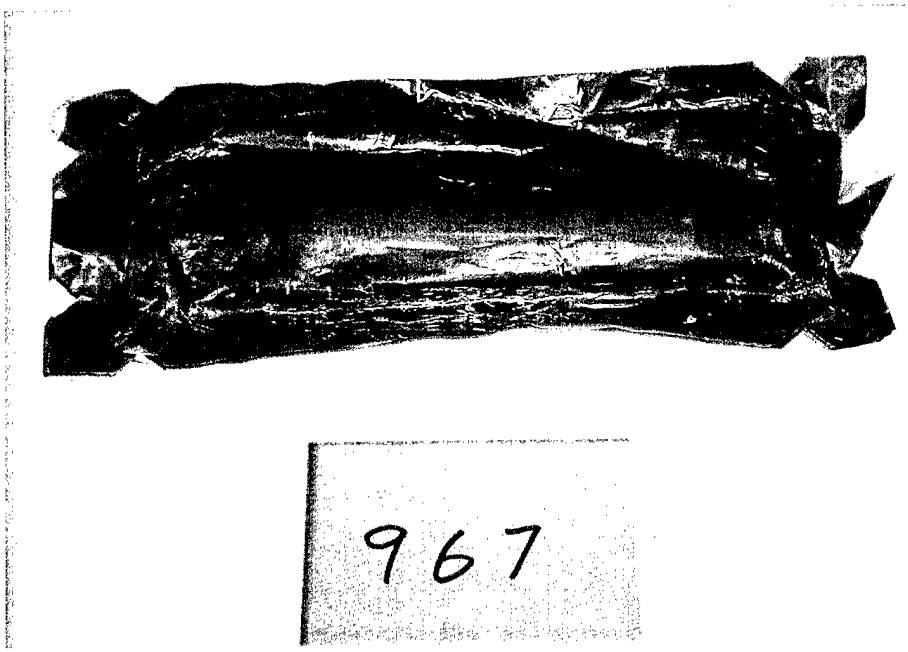

Photo 7. Group B--Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe

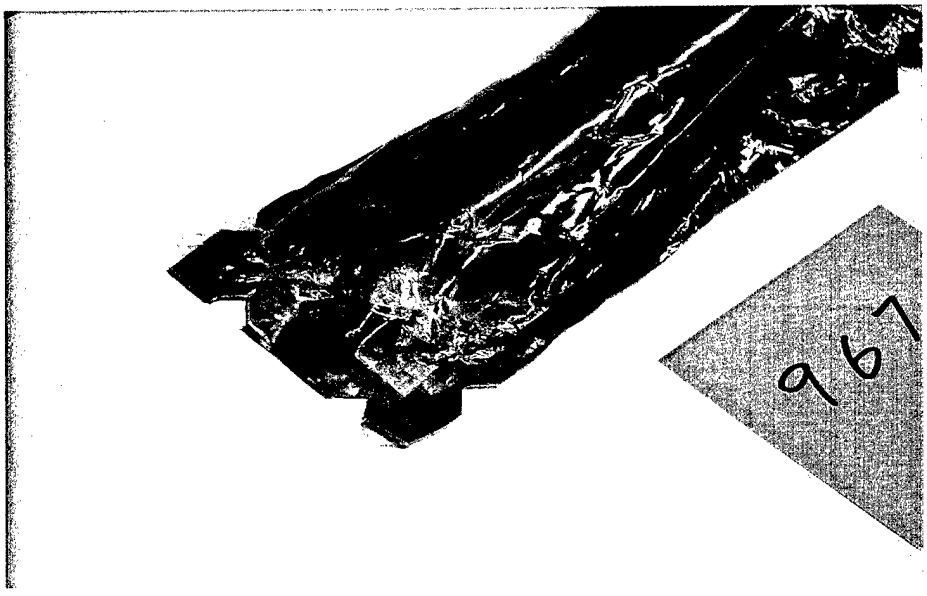

Photo 8. Group B--Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe

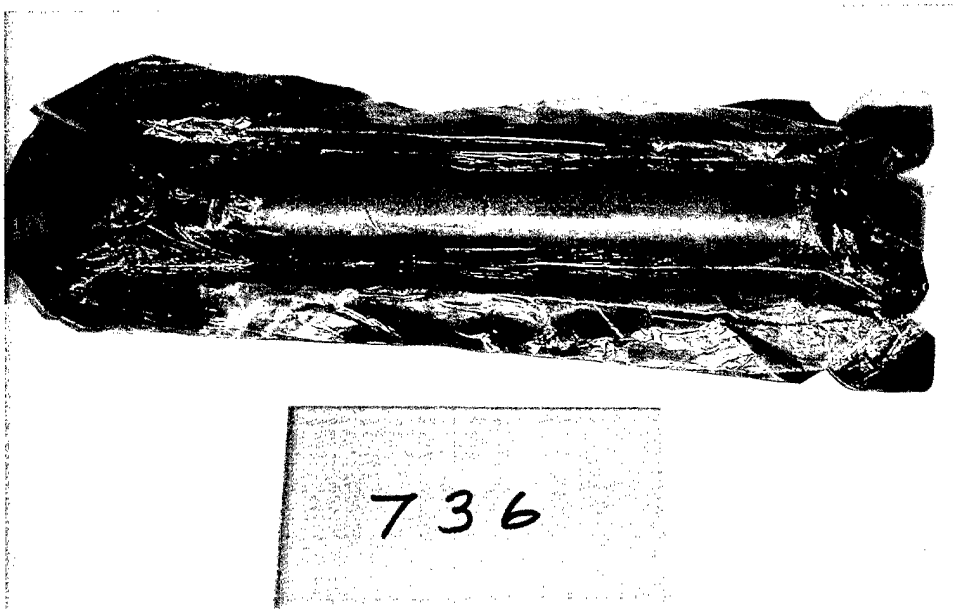

Photo 9. Group C--Package is punctured exposing device

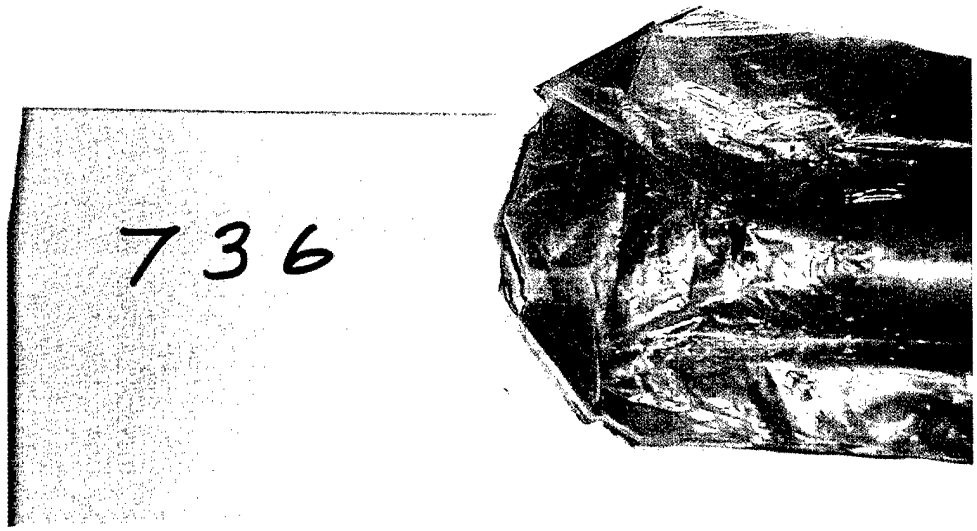

Photo 10. Group C--Package is punctured exposing device

Photo 11. Group D--In relatively good condition, no significant package damage

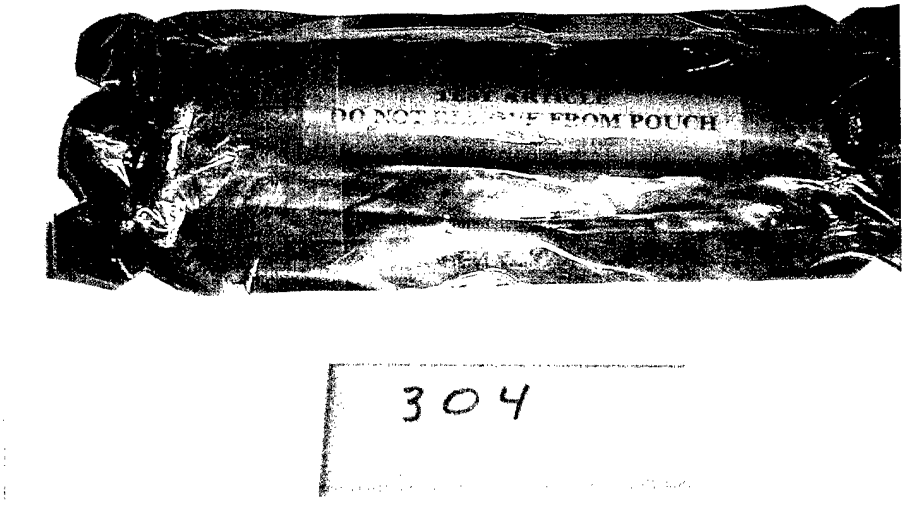

Photo 12. Group D--In relatively good condition, no significant package damage

Appendix B. Protocol 176

Study Title:

Technical Functional Testing of Multi-Chamber Auto Injectors (MA)

STUDY NUMBER: G472506B

Study performed by Battelle Memorial Institute
Product Development Group
505 King Avenue, Building 3
Columbus, Ohio 43201-2693

I. Study Director and Management:

Study Director: Timothy L. Hayes, B.A.
MREF Manager: James E. Estep, Ph.D., D.V.M.

II. Sponsor:

U.S. Army Medical Department Board (USAMEDDBD)
Attn MCCS-FBS, CDR AMEDDC&S
1961 Wilson Street, Fort Sam Houston, TX 78234-6124

III. Introduction:

The Multi-Chambered Auto Injector (MA) is a single autoinjector that contains two medicaments stored separately in one single cartridge (the MA provided for this study will contain a saline solution only). It is a cylindrical shaped device with a length of approximately 18 centimeters (cm) and a diameter of approximately 2.5 cm. The MA has a safety cap on one end and a green end cap on the opposite end. The green end contains the needle. The injection is accomplished by removing the safety cap, placing the green end against the thigh, and pushing hard until the device activates. The USAMEDDBD has designed an Initial Operational Test and Evaluation (IOTE) for the MA devices. This IOTE will result in MA devices being issued to representative soldiers from Armor, Infantry, Special Operations, and Airborne units who will carry them during field training exercises over a 21-30 day period. The IOTE objectives are to collect data to determine:

A. The durability and functionality of the devices when carried by soldiers during tactical maneuvers.

B. The adequacy of training and soldiers' interpretation of instructions located on the device.

C. The soldiers' ability to distinguish the MA device from a similar device that will also be carried by the soldiers.

The MA devices will be collected after being subjected to the 21-30 days of field training exercises, and forwarded to Battelle for testing.

IV. Objectives:

Battelle will conduct technical testing of the devices to determine functionality and physical condition. Laboratory testing will be accomplished using standards established by current Good Laboratory Practices. Battelle will conduct technical testing of not more

than 300 autoinjectors provided by the USAMEDDBD. The testing covered in this protocol does not address any issues involving the material contained within the MA. This testing is only directed at the mechanical properties and physical condition of the device. Testing will include the following measurements and observations:

1. Delivery pressure (Firing force);
2. Volume of delivered saline;
3. Speed of delivery;
4. Needle length;
5. Physical condition of the autoinjector, to include packaging material.

The following protocol provides documentation of the procedures to be followed during this study. This study will be conducted according to the guidelines of the Food and Drug Administration's (FDA) Good Laboratory Practice (GLP) Regulations (21 CFR Part 58).

V. Experimental Design:

A. Test System: No test system as defined by 21 CFR Part 58 Section 58.3(i) will be used. Therefore items such as identification procedures, number, body weight range, sex, source of supply, species, strain, substrain, age, diet, and dosages levels will not be defined in this protocol.

B. Test Device: Is the Multi-Chamber Auto Injectors (MA) as delivered from the Sponsor. The Test Device will be identified using label information provided by the sponsor.

C. Test and Control Article: No Test or Control Article as defined by 21 CFR Part 58 Subpart F will be used. Therefore, identity, strength, purity, stability, storage conditions, expiration date, and composition are not relevant to this study.

D. Test Procedures: The test procedures are described in the following methods for each test conducted by Battelle. Test method No 31 provides a description of the overall testing process:

- Method No.25/Chemistry "Setup of the Fluke 1953A Counter Timer for Testing Multi-Chamber Autoinjectors"

- Method No.26/Chemistry "Setup of the Sensotec DC-DC LVDT for Testing Multi-Chamber Autoinjectors"

- Method No.27/Chemistry "Verification Check of Digital Scale"
- Method No.28/Chemistry "Setup of the Starrett Digital Indicator for Testing Multi-Chamber Autoinjectors"
- Method No.29/Chemistry "Setup of the Chatillon TCD-200 Tension/Compression Tester for Testing Multi-Chamber Autoinjectors"
- Method No.30/Chemistry "Setup of the Graphtec SR6312 Chart Recorder for Testing Multi-Chamber Autoinjectors"
- Method No. 31/Chemistry "Method for Functionality Testing on Multi-chamber Autoinjectors"
- Method No.32/Chemistry "Verification Check of Force Measurements Using LVDT and Strip Chart Recorder"
- Method No.33/Chemistry "Setup of the Keyence LX2-V10W Laser Sensor Digital Display Unit for Testing Multi-Chamber Autoinjectors"

E. Interpretation of Results:

The results will be tabulated from each test method. A statistical analysis of the results will be conducted to help estimate the pass/fail rate of the MA's.

VI. Record Maintenance:

The following records are to be maintained:

A. Test device inventory and related information.

B. Raw data records.

VII. Report:

A final report will be submitted to the sponsor. The report will include Introduction, Materials and Methods, Results, Discussion and Conclusion.

Study Director: Timothy L Hayes 5/2/00
Timothy L Hayes, B.A. Date
Principal Research Scientist

Scientific Review: Lawrence Bullen 5/10/00
Lawrence Bullen, B.S. Date
Research Scientist

Sponsor Review: William "Bill" Owen 5/3/00
Bill Owen Date
Program Manager
U.S. Army MEDD

MREF Manager: James E Estep 5-9-00
James E. Estep, Ph.D., D.V.M. Date
Manager
Medical Research and Evaluation Facility

Reviewed and Registered by: Elisha Morrison 5/10/00
Elisha Morrison, M.S. Date
Senior Quality Assurance Specialist

Appendix C. Methods

METHOD FOR SETUP OF THE FLUKE 1953A COUNTER TIMER FOR TESTING MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedure for setting up the Fluke 1953A Counter Timer for testing multi-chamber autoinjectors as performed under project G472506. This instrument is used to measure time of delivery.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

1. Method No.29-00/Chemistry "Setup of the Chatillon TCD-200 Tension/Compression Tester for Testing Multi-Chamber Autoinjectors"

2. Method No.33-00/Chemistry "Setup of the Keyence LX2-V10W Laser Sensor Digital Display Unit for Testing Multi-Chamber Autoinjectors"

E. MATERIALS AND EQUIPMENT:

Fluke 1953A Counter Timer
Chatillon test stand
Keyence LX2-V10W Digital Display
Keyence laser transmitter and receiver set
Wavetek Model 442 Dual Hi/Lo Filter
Digital Oscilloscope
Digital Function Generator
Instrument log books

F. PROCEDURE:

1. Setup the Chatillon TCD-200 Tension/Compression Tester per reference D.1.

2. Setup the Keyence laser sensor per reference D. 2.

3. Switch settings on the Fluke Counter Timer.

3.1. Set Channel A switches to: "SLOPE –", "DC" and "ATTEN X1".

3.2. Set Channel B switches to: "SLOPE +", "DC" and "ATTEN X1".

3.3. Set the "SEP – COM" switch to "COM".

3.4. Set the "FUNCTION" selector to "T.I. A-B".

3.5. Set the "RANGE" selector to "1.0 S", and the "MODE" switch to "TRIG".

4. Trigger level adjustment:

4.1. Connect the signal output of the Digital Function Generator to the "Channel A" input connection of the Fluke Counter Timer.

4.2. Set the Digital Function Generator to produce a square wave with a frequency of 1 Hz with an amplitude of 300 mv.

4.3. Adjust the "CHANNEL A" "TRIGGER LEVEL".

4.3.1. Rotate the trigger level adjustment fully counter-clockwise.

4.3.2. Rotate clockwise until the trigger status indicators start to blink on and off.

4.3.3. Rotate counter-clockwise until the trigger status indicators stop blinking.

4.3.4. Very slowly rotate clockwise until the trigger status indicators blink consistently.

4.3.5. Check the setting by reducing the amplitude on the function generator in 10 mv steps until the trigger status indicators stop blinking.

4.3.6. When adjusted correctly, the Fluke Counter Timer should trigger consistently on a 300 mv signal and not trigger on a 250 mv signal.

4.4. Repeat step 4.3 for the "CHANNEL B" "TRIGGER LEVEL".

4.5. Disconnect the Digital Function Generator.

5. Connect and set switches on the Wavetek Model 442 Dual Hi/Lo Filter.

5.1. Connect the output from the Keyence LX2-V10W Digital Display unit to input number 1 of the Wavetek Filter.
5.2. Set the filter cutoff frequency to 10K Hz.

5.3. Set the filter switches to: "LO PASS", "20dB GAIN" and "FLAT AMPL".

5.4. Connect Output 1 of the Wavetek Filter to the Channel A input of the Fluke 1953A Counter Timer.

6. Turn on the Keyence Laser Sensor and the Wavetek Filter.

7. Press the "ZERO" button on the Keyence display unit.

8. Check the operation of the Laser Sensor and the Fluke Counter Timer.

8.1. Press the "Reset" button on the Fluke Counter Timer.

8.2. Pass a small object (a pen for example) through the laser beam.

8.3. The Fluke Counter Timer should trigger and display the time that the object blocked the beam.

8.4. If adjusted correctly, the Fluke Counter Timer should detect an object as small as a human hair when passed through the beam.

8.5. A ¼" diameter ball dropped through the beam from a height of 1.5 inches, should register a time of 0.012 sec.

8.6. If the Fluke Counter Timer does not detect these objects properly, recheck the set up of the Keyence Laser Sensor, the Wavetek Filter and the Fluke Counter Timer.

9. Document instrument set up.

10. The Fluke Counter timer is calibrated annually when in use.

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Registered By Elisha Morrison 5/10/00
Elisha N. Morrison. M.S. Date

METHOD FOR SETUP OF THE SENSOTEC DC-DC LVDT FOR TESTING MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedure for setting up the Sensotec DC-DC LVDT for testing multi-chamber autoinjectors as performed under project G472506. This instrument generates a signal which is displayed on the chart recorder.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

LVDT: Linear Voltage Displacement Transformer

D. REFERENCES:

1. Method No.29–00/Chemistry "Setup of the Chatillon TCD-200 Tension/Compression Tester for Testing Multi-Chamber Autoinjectors"

2. Wiring diagram for Sensotec DC-DC LVDT

3. Method No.30–00/Chemistry "Setup of the Graphtec SR6312 Strip Chart Recorder for Testing Multi-Chamber Autoinjectors".

E. MATERIALS AND EQUIPMENT:

Chatillon TCD-200 Tension/Compression Tester
Spring scale head adapter
Chatillon spring scale
Sensotec +/-2 inch DC-DC LVDT

F. PROCEDURE:

1. Mount the LVDT to the spring scale head adapter on the TCD-200, refer to reference D.1.

2. Connect the LVDT input power leads to a suitable DC power supply, refer to reference D.2.

3. Adjust the range on the strip chart recorder to 5 volts full scale, refer to reference D.3.

4. Connect the LVDT output leads to the strip chart recorder.

5. Turn on the strip chart recorder and the power supply for the LVDT.

6. Manually move the core of the LVDT by compressing the spring in the spring scale and observe the motion of the pen on the strip chart recorder. Adjust the Bias on the strip chart recorder so that the pen motion stays on the chart through small (not more than 5 pounds) deflections of the spring scale.

7. Adjust the LVDT by loosening the clamp holding the barrel of the LVDT and sliding the barrel up or down so that the range of motion represented by 0 to 10 pounds on the spring scale is approximately –5 to 0 volts output from the LVDT. It is important that the zero position of the spring scale is not out side of the –5 to 0 volts range of the LVDT.

8. Tighten all fasteners.

9. Move the ram on the Chatillon TCD200 to its full up position.

10. Mount the Chatillon Digital Force gage on the autoinjector support stand.

11. Move the ram on the Chatillon TCD200 downward until it is slightly above the tip on the Digital Force Gage.

12. Set the feed rate on the Chatillon TCD200 to its minimum feed of 0.5 in/min.

13. Start the chart on the strip chart recorder.

14. Start the Chatillon TCD200 in the downward direction until the digital force gage reads approximately 10 pounds.

15. Stop the strip chart recorder.

16. The trace on the strip chart should be a straight sloped line from the point where the LVDT first moved to the point where it stopped.

17. If the trace is not straight, i.e. the slope changes near the beginning of the LVDT motion, it is an indication that the LVDT is not operating fully in its linear range and that it must be adjusted. To correct this, move the barrel of the LVDT downward in its clamp by a small amount (1/4 inch). Repeat steps 13 through 17.

18. Refer to reference D.3. for instructions on setting the gain and bias on the strip chart recorder.

19. If it is not possible to establish a straight line output from the LVDT, get assistance from an electronics technician.

20. Document instrument set up.

21. The Sensotec is calibrated annually when in use.

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METHOD FOR VERIFICATION CHECK OF DIGITAL SCALE

A. PURPOSE:

To describe the procedure used to verify a scale's accuracy between annual calibrations.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

None.

E. MATERIALS AND EQUIPMENT:S

Digital scale
Instrument Log Book
Weight set
Weight lifter
Lint free wipes

F. PROCEDURE:

Follow the instructions below for performing a verification check daily, prior to use.

1. Weights shall be handled in the following manner:

   1.1 Weights will be handled only with the proper tweezers. Avoid contact with hands.

   1.2 Weights will be removed from their case and placed on scale and returned directly to case after use. This action is to insure the integrity of weights by avoiding damage and/or soiling.

   1.3 If weights are to be cleaned, only lint free wipes shall be used.

2. Use the following sequence to verify scale calibration.

   2.1 Be sure scale is secure and level.

2.2. Turn scale on. Scale must be turned on for at least 30 minutes prior to calibration verification.

2.3. Tare scale.

2.4. Place 1 gram weight on scale. Scale should read 1.000 ± 0.005.

2.5. Remove weight from scale and tare.

2.6. Place 20 gram weight an scale. Scale should read 20.000 ± 0.005.

2.7. Remove weight from scale and tare.

2.8. Place 50 gram weight on scale. Scale should read 50.000 ± 0.005.

2.9. Remove weight from scale.

3. If readings within the specified range can not be obtained, check the scale to be sure it is secure and level. If there is a question about the accuracy of the scale, it must be recalibrated.

4. An entry shall be made in the appropriate instrument specific log book, listing the date, technician, statement of verification, "passed" or "failed", calibration check and standard weight set identification number.

5. In addition to calibration verification, an annual calibration schedule shall be maintained, when in use.

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METHOD FOR SETUP OF THE STARRETT DIGITAL INDICATOR FOR TESTING MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedure for setting up the Starrett Digital Indicator for testing multi-chamber autoinjectors as performed under project G472506. This instrument is used to measure needle length.

B. SCOPE:

Limited to the setup used for testing Autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

Starrett Operating Manual, Wisdom Plus Series Electronic Indicators

E. MATERIALS AND EQUIPMENT:

Starrett Digital Indicator
Indicator needle length measurement adapter
Instrument log books

F. PROCEDURE:

1. Mount the indicator needle length measurement adapter on to the spindle housing of the indicator. Secure with two clamping screws.

2. Be sure that the indicator moves smoothly through its entire range and that it is not dragging on the inside of the adapter. If there is any contact, loosen the clamp screws and reposition the adapter until the indicator moves freely.

3. Mount the indicator to a heavy base.

4. Turn the indicator on

5. Turn off the "Feature Lock" if it is on. A small key symbol appears at the lower left of the display if "Feature Lock" is on.

5.1 Press and hold [Move 2nd] until 2nd appears at the bottom of the display, then release.

5.2 Press and release [On/Clr] within 3 seconds.

5.3 Press and release [Tol] within 3 seconds.

5.4 The same sequence toggles "Feature Lock" on.

6. Reset the indicator to default settings.

6.1 Press and hold [Move 2nd] until 2nd appears at the bottom of the display

6.2 Press and release [On/Clr] within 3 seconds.

6.3 Press and release [Chng] within 3 seconds.

7. If "IN" appears at the bottom of the display, the unit is set to read in inches. Set the indicator to read in millimeters.

7.1 Press and hold [Move 2nd] until 2nd appears at the bottom of the display.

7.2 Press and release [Tol] within 3 seconds.

8. Set the indicator's resolution to 0.02 mm

8.1 Press and hold [Move 2nd] until 2nd appears at the bottom of the display.

8.2 Press and release [On/Clr] within 3 seconds.

8.3 Press and release [Hold] within 3 seconds.

8.4 Press and release [Chng] to step through the available resolution options until 5 appears in the display.

8.5 Press and release [Chng] and [Move 2nd] simultaneously.

9. Set the indicator to zero at the end of the needle length measurement adapter.

9.1 Use a ground steel flat surface to push the indicator anvil in until the ground surface is flat against the end of the adapter.

9.2 Press the [On/Clr] button while holding the ground surface against the end of the adapter.

10. Set the indicator to the "Hold Max" mode. Press and hold [Hold] until cursor moves under "Max".

    10.1 Turn on the "Feature Lock".

    10.2 Press and hold [Move 2nd] until 2nd appears at the bottom of the display, then release.

    10.3 Press and release [On/Clr] within 3 seconds

    10.4 Press and release [Tol] within 3 seconds

    10.5 The same sequence toggles "Feature Lock" off.

11. Document instrument set up.

12. The Starret digital indicator is calibrated annually when in use.

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METHOD FOR SETUP OF THE CHATILLON TCD-200 TENSION/COMPRESSION TESTER FOR TESTING MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedure for setting up the Chatillon TCD-200 Tension/Compression Tester for testing multi-chamber autoinjectors as performed under project G472506. This device is also referred to as the pull tester.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

1. Chatillon TCD-200 Instruction Manual

2. Keyence laser thrubeam sensor Instruction Manual

E. MATERIALS AND EQUIPMENT:

Chatillon TCD-200 Tension/Compression Tester
Autoinjector support stand
Spring scale head adapter
Chatillon spring scale
Sensotec +/- 2 inch DC-DC LVDT
Keyence laser thrubeam sensor head
Instrument log books

F. PROCEDURE:

1. Set the manually adjustable travel limits to allow maximum travel.

2. Move the ram to a position near the center of its travel.

3. Mount the Autoinjector support stand using one 10-32 screw through its base into the base of the TCD-200.

4. Mount the laser thrubeam sensor head source and detector on the support arm of the autoinjector support stand.

5. Mount the spring scale head adapter to the gage mount using three 10-32 screws.

6. Clamp the spring scale and the LVDT in the spring scale head adapter such that the spring scale extends below the clamp about two inches and its graduations are facing the front. The bottom of the LVDT should be approximately even with the bottom of the spring scale.

7. Mount the spring scale end adapter on the spring scale and screw the LVDT core into the threaded hole in the arm of the end adapter. The spring scale end adapter must be adjusted to allow the LVDT core to be centered in the LVDT and move with no resistance.

8. Document instrument set up.

9. This instrument is calibrated every two years when in use.

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METHOD FOR SETUP OF THE GRAPHTEC SR6312 CHART RECORDER FOR TESTING MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedure for setting up the Graphic SR6312 Chart Recorder for testing multi-chamber autoinjectors as performed under project G472506.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

1. Method No.29–00/Chemistry "Setup of the Chatillon TCD-200 Tension/Compression Tester for Testing Multi-Chamber Autoinjectors"

2. Method No.32–00/Chemistry "Verification Check of Force Measurements Using LVDT and Strip Chart Recorder"

E. MATERIALS AND EQUIPMENT:

Graphtec SR6312 Chart Recorder
Sensotec +/- 2 inch DC-DC LVDT
DC power supply
Chatillon TCD-200 Tension/Compression Tester
Chatillon digital force gage with mounting adapter
Chatillon spring scale
Autoinjector support stand
Instrument log books

F. PROCEDURE:

1. Setup the Chatillon TCD-200 Tension/Compression Tester per the instructions in reference D.1.

2. Move the ram of the Chatillon tester to its highest position.

3. Insert the mounting adapter attached to the back of the Chatillon digital force gage into the slot in the back of the Autoinjector support stand. You may need to

manually raise the adapter on the spring scale in order for the digital force gage to be installed.

4. Be sure that the digital force gage mounting adapter is sitting securely on it's stop and that the power cord is not being severely bent or taking any of the load.

5. Connect the output leads of the LVDT to the signal input of the chart recorder.

6. Set the range on the chart recorder to 5 volts full scale.

7. Adjust the "Bias" and "Cal." on the chart recorder so that full scale deflection corresponds to 0 to 10 pounds on the digital force gage.

   Note: The chart paper may have printed numbers ranging from 0 to 10 starting from either the right or the left or both. All references to the scale on the chart recorder refer to 0 at the left edge of the chart and 10 at the right edge of the chart.

   7.1 Move the ram of the Chatillon TCD200 down until the adapter on the spring scale is just above the digital force gage.

   7.2 Set the speed on the Chatillon TCD200 to its minimum.

   7.3 Start the Chatillon TCD200 in the downward direction.

   7.4 Stop the motion when the digital force gage reads 10 pounds.

   7.5 Adjust the "Bias" so the pen is at 10 on the chart recorder.

   7.6 Start the Chatillon TCD200 in the upward direction.

   7.7 Stop the motion when the digital force gage reads 0 pounds.

   7.8 Adjust the "Cal." so the pen is at 0 on the chart recorder.

   7.9 Repeat this process until the 10 pound deflection of the force gage produces a full scale deflection of the chart recorder within +/- 0.05 units (1/2 of the small divisions) on the chart recorder. Always adjust the "Bias" when the force gage is at 10 pounds and the "Cal." when the force gage is at 0 pounds.

8. Perform a full scale calibration check as described in reference D.2.

9. Document setup and calibration check.

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METHOD FOR FUNCTIONALITY TESTING ON MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedures used to test the functionality of multi-chamber Autoinjectors

B. SCOPE:

Limited to the testing of autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

1. Method No.25–00/Chemistry "Setup of the Fluke 1953A Counter Timer for Testing Multi-Chamber Autoinjectors"
2. Method No.26–00/Chemistry "Setup of the Sensotec DC-DC LVDT for Testing Multi-Chamber Autoinjectors"
3. Method No.28–00/Chemistry "Setup of the Starrett Digital Indicator for Testing Multi-Chamber Autoinjectors"
4. Method No.29–00/Chemistry "Setup of the Chatillon TCD-200 Tension/Compression Tester for Testing Multi-Chamber Autoinjectors"
5. Method No.30–00/Chemistry "Setup of the Graphtec SR6312 Chart Recorder for Testing Multi-Chamber Autoinjectors"
6. Method No.33–00/Chemistry "Setup of the Keyence LX2-V10W Laser Sensor Digital Display Unit for Testing Multi-Chamber Autoinjectors"
7. Method No.27–00/Chemistry "Verification Check of Digital Scale"
8. Method No.32–00/Chemistry "Verification Check of Force Measurements Using LVDT and Strip Chart Recorder"

E. MATERIALS AND EQUIPMENT:

Chatillon TCD-200 Tension/Compression Tester
Autoinjector support stand
Spring scale head adapter
Chatillon spring scale
Sensotec +/-2 inch DC-DC LVDT
DC power supply
Starrett Digital Indicator
Indicator needle length measurement adapter
Graphtec SR6312 Chart Recorder
Keyence LX2-V10W Laser Sensor
Fluke 1953A Counter Timer
Wavetek 442 Dual Hi/Lo Filter
Digital Oscilloscope
Digital Function Generator
Digital scale
Chatillon digital force gage with mounting adapter
Weight set
Weight lifter
Lint free wipes
Instrument Log Book

F. PROCEDURE:

1. Assemble test equipment per the methods in references D. 1 through 6.

2. Perform daily instrumentation setup and calibration checks as described in references D. 7 and D.8.

   2.1 Check the operation of the Fluke Counter Timer by dropping a 0.25 inch ball through the laser sensor from the top of the autoinjector support stand. If the timer does not read between 0.011 to 0.013 seconds, its trigger settings must be checked.

3. Set the Chatillon travel limits and feed rate.

   3.1 Place an already discharged autoinjector on the support stand on the Chatillon. Bring the Chatillon ram down onto the autoinjector until the adapter on the spring scale holds the end of the autoinjector but is not applying force to it.

   3.2 Press [ZERO DEF]. This sets the current position to zero.

3.3 Press [SET], then [DEF HIGH], then [0] and [ENTER]. This sets the high travel limit to zero.

3.4 Press [SET], then [DEF LOW], then [-] [2] [0] [0] [0] and [ENTER]. This sets the low travel limit to –2 inches.

3.5 If "LIMIT" does not appear in the top of the upper display, press [LIMIT]. This turns on the travel limit function.

3.6 Set the feed rate to 5 inches per minute.

4. Set the digital indicator to hold the maximum reading.

4.1 Turn on the indicator.

4.2 Set the indicator to zero by depressing the indicator's anvil with a flat surface pressed against the end of the needle length adapter and then pressing [ON/CLR].

4.3 Set the hold maximum mode by depressing [HOLD] until the small cursor appears under "MAX".

5. Assemble units to be tested.

5.1 Clear testing area of any materials or injectors from previous batches.

5.2 Label all pans or bags.

6. Functionality testing.

6.1 Record the serial number of the autoinjector.

6.2 Examine protective packaging for signs of damage.

6.2.1 Record observations of damage to the unopened package.

6.2.2 Photograph unopened package if damage appears likely to compromise function of the autoinjector.

6.3 Remove autoinjector from the protective packaging and examine unit for damage.

6.3.1 Record observations of damage to the autoinjector.

6.3.2 Photograph autoinjector if damage appears likely to compromise functioning.

6.4 Remove the gray safety cap and discard it.

6.5 Place the autoinjector on the digital scale and record initial weight to the nearest 0.001 g.

6.6 Place the autoinjector on the support stand on the Chatillon tester, prepare the instrumentation for the test and execute the test.

6.6.1 Reset the timer.

6.6.2 Start the strip chart.

6.6.3 Start the Chatillon feeding in the downward direction.

6.6.4 Stop the Chatillon as soon as the autoinjector fires.

6.7 Record test results.

6.7.1 Record the Firing Force (FF) from the chart recorder. The FF is read at the transition from the straight steadily increasing force to the near instantaneous increasing force. The FF should be recorded to the nearest 0.1 pound (the smallest unit on the strip chart). (See attached Figure 1).

6.7.2 Record the Time of Delivery (TD) from the timer to the nearest 0.01 second.

6.7.3 Start the Chatillon tester in the upward direction until the autoinjector can be removed from the test stand.

6.7.4 Remove any droplets of solution from the tip of the needle.

6.7.5 Insert the needle into the needle length adapter on the digital indicator and record the maximum value as the Needle Length (NL) to the nearest 0.01mm.

6.7.6 Place the autoinjector on the digital scale and record the Final Weight to the nearest 0.001g.

6.8 Record any abnormalities observed during the test.

6.9 Place the autoinjector in a suitable disposal container.

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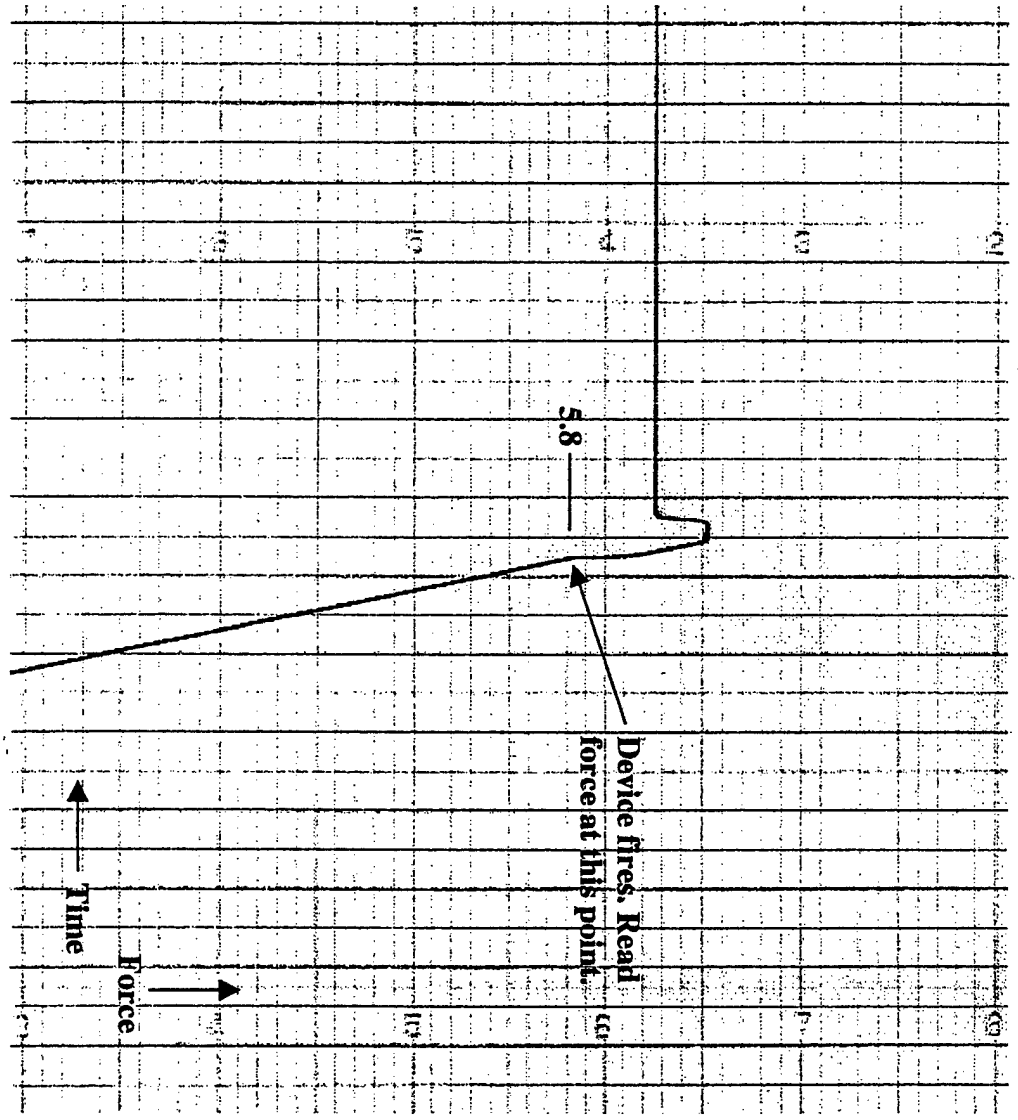

Figure 1

METHOD FOR VERIFICATION CHECK OF FORCE MEASUREMENTS USING LVDT AND STRIP CHART RECORDER

A. PURPOSE:

To describe the procedure used to verify the accuracy of the force measurement acquired by plotting the output of an LVDT to a strip chart recorder.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

LVDT: Linear Voltage Displacement Transformer

D. REFERENCES:

None.

E. MATERIALS AND EQUIPMENT:

Chatillon test stand
Chatillon digital force gage with mounting adapter
Chatillon spring scale
DC-DC LVDT, +/- 2 travel
Strip chart recorder
Autoinjector support stand
Instrument log books

F. PROCEDURE:

The calibration verification of the strip chart recorder is performed using a calibrated digital force gage. The gage is calibrated annually when in use. Follow the instructions below for performing a verification check daily, prior to use.

1. Instrumentation setup and warm up.

   1.1 Turn on the power to the Chatillon tester, the LVDT, the strip chart recorder and the digital force gage and allow the devices to warm up for a minimum of 30 minutes.

   1.2 Move the ram of the Chatillon tester to its highest position.

1.3 Insert the mounting adapter attached to the back of the Chatillon digital force gage into the slot in the back of the autoinjector support stand. You may need to manually raise the adapter on the spring scale in order for the digital force gage to be installed.

1.4 Be sure that the digital force gage mounting adapter is sitting securely on it's stop and that the power cord is not being severely bent or taking any of the load.

1.5 Zero the digital force gage.

1.6 Zero the strip chart recorder, the strip chart should be running while adjusting the zero. Stop the strip chart.

1.7 Bring the ram of the Chatillon tester down until the adapter on the spring scale is engaged on the anvil on the digital force gage but not touching. The force gage should still read zero, raise the ram on the Chatillon tester if necessary.

1.8 Set the strip chart recorder speed to around 1 in/min or 25 mm/min.

1.9 Set the Chatillon tester feed rate to its minimum value of 0.5 in/min.

2. Verifying the calibration.

2.1 Start the strip chart.

2.2 Start the Chatillon tester in the downward direction until the digital force gage reads 2.00. If you overshoot the desired value by more than +/- 0.04, run the tester up and then approach the target value again in the downward direction.

2.3 Record the reading on the digital force gage to two decimal places and the strip chart recorder to the nearest 0.1 pound.

2.4 Repeat steps 2.2 and 2.3 at two pound increments up to 10 pounds.

3. If the value recorded from the strip chart recorder varies by more than 0.05 pound from that recorded from the digital gage, the strip chart recorder must be adjusted to be within 0.05 pounds over the entire range. If the strip chart recorder can not be adjusted to be with 0.05 pounds of the digital gage, the equipment cannot be used.

4. Record date, technician, statement of "passed" or "failed" and the identification number of the digital force gage used as the standard.

5. In addition to calibration verification, an annual calibration schedule shall be maintained for the strip chart recorder.

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METHOD FOR SETUP OF THE KEYENCE LX2-V10W LASER SENSOR DIGITAL DISPLAY UNIT FOR TESTING MULTI-CHAMBER AUTOINJECTORS

A. PURPOSE:

To describe the procedure for setting up the Keyence LX2-V10W Laser Sensor Digital Display Unit for testing multi-chamber autoinjectors as performed under project G472506. This unit is used to measure time of delivery.

B. SCOPE:

Limited to the setup used for testing autoinjectors under project G472506.

C. DEFINITIONS:

None.

D. REFERENCES:

Keyence Instruction Manual, Digital Display Compact Laser Thrubeam Sensor, LX2-V10W Series.

E. MATERIALS AND EQUIPMENT:

Keyence LX2-V10W Digital Display
Keyence laser transmitter and receiver set
Chatillon TCD-200 Tension/Compression Tester
Autoinjector support stand

F. PROCEDURE:

1. Read the warnings, cautions and safety precautions in the Keyence Instruction Manual.

2. The LX2-V10W Digital Display unit should be wired to an appropriate power supply and connected to the laser transmitter and receiver set per the instructions in the Keyence Instruction Manual.

3. Align the optical axes of the laser transmitter and receiver per the instructions in the Keyence Instruction Manual.

4. Initialize the LX2-V10W Digital Display unit. This resets the unit to the default factory settings.

4.1 Hold down the [SET] and [↵] keys and turn the key-operated power switch to the on position. "U-_ _" should appear on the display.

4.2 Press the [↵] key. "END" should be displayed.

4.3 Turn the power switch off and back on.

5. Activate the "Auto Scaling Function". This compensates for ambient conditions and mounting errors. This procedure should be repeated any time that the mounting is adjusted or disturbed.

5.1 Press the [SET] key for 3 seconds. "ABCD" should be displayed.

5.2 The "A" should be flashing, if it is not, press the [➢] key to step through the options.

5.3 Press the [↵] key when the "A" is flashing.

5.4 Press the [➢] until "A-0" is displayed. This sets the unit to display a percentage value between 0 and 100% proportional to the light being received by the receiver.

5.5 Press the [↵] key.

5.6 Press the [SET] key. The display should show a value near 100%.

6. Press the [ZERO] key. This sets the current level to 0 and sets the unit to display a range of –100 to 0%.

7. Check the operation by placing an object between the laser transmitter and receiver. The display should show a negative value approaching –100 as the full beam is blocked.

8. Document instrument set up.

Originator: Lawrence Bullen 5/10/00
Lawrence Bullen, BSME Date

Reviewed By: John Tallarico 10/May/2000
John P. Tallarico, Master Research Tech Date

Reviewed By: Diane Sotos 5/10/00
Diane P. Sotos, Project Specialist Date

Registered By Elisha Morrison 5/10/00
Elisha N. Morrison. M.S. Date

Appendix D. Data Sheets

Autoinjector Functionality Testing
Study Number: G472506B

Firing Force (FF)		Dispensed Volume Saline (DV)	
Method Followed:	Method No.31-00/Chemistry	Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Graphtec SR6312 Chart Recorder	Instrument Used:	Scaltec Digital Scale SBA41
ID/Serial Number:	LN462090	ID/Serial Number:	C17157
		Solution Density:	1.0046 g/mL

Time of Delivery (TD)/Speed of Delivery		Needle Length (NL)	
Method Followed:	Method No.31-00/Chemistry	Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Fluke 1953A Counter Timer	Instrument Used:	Starrett Digital Indicator F2730-1
ID/Serial Number:	LN244927	ID/Serial Number:	000076025

Physical Condition of the Auto Injector, to include packaging material i.e. intact, etc.)	Method Followed: Method No.31-00/Chemistry

Setup Performed by:	Lawrence Butler	Date: 5/10/00

Autoinjector Functionality Testing

Study Number: G472506B

Code Definitions:

Package Condition Codes:

A = End of package has been opened and then taped closed to prevent device from falling out of package.
B = Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe.
C = Package is punctured exposing device.
D = In relatively good condition, no significant package damage.

Device Condition Codes:

E = No apparent damage.
F = Some damage observed, see Comments column. Additional comments may be found on the last page of this series of tests. Comments are listed by Serial Number.

Codes for Any Additional Comments (Initial and Date)

Operated by: NA	Date: NA	Data Recorded/Witnessed by: NA	Date: NA
Reviewed by: NA	Date: NA	Data Key Entered by: NA	Date: NA

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
895	B	E	32.361	29.606	5.3	3.00	19.16	
78	B	E	32.381	29.591	6.0	2.58	19.98	
42	B	E	32.245	29.480	5.5	2.67	19.98	
114	B	E	32.435	29.708	6.4 WN ~~6.3~~ 5/16/00	2.60	20.32	
509	B	E	32.090	29.338	5.1	2.73	20.10	
622	B	E	32.154	29.414	5.6	2.42	20.26	
894	B	E	32.276	29.543	6.0	2.47	19.68	
930	B	E	32.347	29.598	6.5	/	19.90	no data due to instrument/ operator error 5/10/00

Operated by: Lawrence Bullen	Date: 5/10/00	Data Recorded/Witnessed by:	Date: 5/10/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/11/00

WN: Wrong Number
Data verified with strip chart 5/31/00

Autoinjector Functionality Testing

Study Number: G472506B

Comments continued, listed by serial number (initial and date each comment)

Operated by: NA	Date: NA	Data Recorded/Witnessed by: NA	Date: NA
Reviewed by: NA	Date: NA	Data Key Entered by: NA	Date: NA

Autoinjector Functionality Testing
Study Number: G472506B

Firing Force (FF)	
Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Graphtec SR6312 Chart Recorder
ID/Serial Number:	LN462090

Dispensed Volume Saline (DV)	
Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Scaltec Digital Scale SBA41
ID/Serial Number:	C17157
Solution Density:	1.0046 g/mL

Time of Delivery (TD)/Speed of Delivery	
Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Fluke 1953A Counter Timer
ID/Serial Number:	LN244927

Needle Length (NL)	
Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Starrett Digital Indicator F2730-1
ID/Serial Number:	000076025

Physical Condition of the Auto Injector, to include packaging material i.e. intact, etc.)	Method Followed: Method No.31-00/Chemistry

Setup Performed by:	Lawrence Bullen	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Code Definitions:

Package Condition Codes:

A = End of package has been opened and then taped closed to prevent device from falling out of package.
B = Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe.
C = Package is punctured exposing device.
D = In relatively good condition, no significant package damage.

Device Condition Codes:

E = No apparent damage.
F = Some damage observed, see Comments column. Additional comments may be found on the last page of this series of tests. Comments are listed by Serial Number.

Codes for Any Additional Comments (Initial and Date)

Operated by: na	Date: na	Data Recorded/Witnessed by: na	Date: na
Reviewed by: na	Date: na	Data Key Entered by: na	Date: na

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
254	B	E	32.252	29.511	6.0	2.46	20.12	
292	B	E	32.404	29.666	5.1	2.58	20.08	
279	B	E	32.400	29.570	6.3	2.60	19.72	
228	B	E	32.024	29.300	5.3	2.57	19.98	
866	B	E	32.473	29.744	5.1	2.61	19.92	
905	B	E	32.282	29.535	5.9	2.29	19.66	
797	B	E	32.194	29.435	5.1	2.63	20.08	
722	B	E	32.436	29.708	5.5	2.54	19.76	
334	B	E	32.141	29.304	6.2	2.58	20.20	
427	B	E	32.422	29.725	5.3	2.64	20.40	

Operated by: Lawrence Ballon	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Ballon	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
37	B	E	32.354	29.449	5.5	2.50	19.84	
538	B	E	32.208	29.493	5.7	2.45	19.78	
853	B	E	32.294	29.553	4.5	2.58	19.86	
284	B	E	32.358	29.592	6.0	2.59	20.00	
447	B	E	32.234	29.532	6.0	2.58	19.18	
645	B	E	32.207	29.416	5.9	3.03	20.12	
315	B	E	32.214	29.402	5.8	2.63	19.86	
819	B	E	32.416	29.675	5.7	2.51	20.18	
852	B	E	32.174	29.456	5.7	2.47	20.04	
455	B	E	32.509	29.803	5.8	2.56	20.04	

Operated by: Lawrence Bullon	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullon	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
300	B	E	32.307	29.471	5.6	2.84	19.86	
757	B	E	32.266	29.509	5.7	2.50	20.20	
341	B	E	32.208	29.498	6.1	2.53	20.26	
752	B	E	32.266	29.574	6.2	2.50	20.38	
404	B	E	32.159	29.429	5.5	2.43	19.96	
73	B	E	32.259	29.504	5.7	2.66	20.10	
941	B	E	32.418	29.567	6.0	2.56	20.12	
735	B	E	32.226	29.514	6.0	2.41	20.16	
390	B	E	32.291	29.554	5.1	2.58	19.90	
361	B	E	~~32.210~~ WN 32.211	29.494	6.0	2.63	20.14	

5/11/00

Operated by: Lawrence Bullar	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/11/00

WN = wrong number

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
82	B	E	32.405	29.749	4.8	4.14	19.46	
171	B	E	32.261	29.544	4.6	2.61	19.98	
825	B	E	32.290	29.525	5.8	2.66	19.72	
386	B	E	32.423	29.693	5.1	2.62	20.14	
412	C	E	32.427	29.563	5.8	2.47	20.02	
898	B	E	32.301	29.445	6.2	2.64	19.78	
442	B	E	32.270	29.534	5.6	2.60	20.28	
789	B	E	32.348	29.600	5.7	2.52	20.24	
131	B	E	32.194	29.458	4.8	2.31	20.24	
448	B	E	32.361	29.495	6.0	2.72	20.20	

Operated by: John Talbacia	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
972	B	E	32.293	29.542	5.7	2.70	19.64	
314	B	E	32.290	29.402	5.7	2.62	19.14	
276	B	E	32.242	29.563	6.2	2.47	20.02	
614	B	E	32.183	29.444	5.4	2.63	19.70	
574	B	E	32.288	29.540	6.1	2.46	19.96	
981	B	E	32.249	29.529	6.0	2.57	19.52	
242	B	E	32.324	29.644	5.5	2.37	19.54	
405	B	E	32.224	29.467	6.4	2.60	19.96	
93	B	E	32.298	29.549	6.1	2.39	20.18	
113	B	E	32.370	29.594	5.7	2.46	19.58	

Operated by: John Tallarico	Date: 11/May/2000	Data Recorded/Witnessed by: Oscar Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
303	B	E	32.128	29.395	5.5	3.24	20.06	
186	B	E	32.242	29.506	6.4	2.58	19.94	
212	B	E	32.224	29.497	5.4	2.57	19.98	
850	B	E	32.157	29.441	WN LB 5/16/00 ~~5.2~~ 5.0	2.41	20.00	
280	B	E	32.168	29.434	5.7	2.50	19.96	
29	B	E	32.477	29.796	5.6	2.56	20.06	
324	B	E	32.209	29.417	4.6	2.65	19.66	
606	B	E	32.215	29.467	5.4	2.60	19.54	
506	B	E	32.312	29.570	5.3	2.58	20.20	
91	B	E	32.526	29.791	5.3	2.58	20.34	

Operated by: John Tallarico	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Buller	Date: 5/11/00

WN: Wrong Number
verified with strip chart LB 5/31/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
273	B	E	32.143	29.299	5.8	2.86	19.84	
823	B	E	32.346	29.604	3.8	2.55	19.88	
368	B	E	32.234	29.519	5.9	2.43	19.96	
463	B	E	32.289	29.550	5.3	2.57	19.60	
897	B	E	32.396	29.674	5.9	2.32	19.98	
320	B	E	32.193	29.429	5.4	2.63	19.84	
252	B	E	32.336	29.520	6.3	2.55	19.82	
301	B	E	32.387	29.656	5.1	2.56	20.14	
882	B	E	32.264	29.382	6.2	2.71	19.92	
686	B	E	32.359	29.613	5.4	2.53	20.36	

Operated by: Lawrence Bullen	Date: 5/11/00	Data Recorded/Witnessed by: Diane Sotus	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
957	B	E	32.292	29.590	5.7	3.74	20.36	
621	B	E	32.108	29.379	5.3	3.06	19.60	
468	B	E	32.195	29.470	5.2	2.67	19.82	
751	B	E	32.345	29.611	5.6	2.63	19.44	
337	B	E	32.322	29.506	5.6	2.76	19.74	
814	B	E	32.202	29.487	5.8	2.60	19.74	
336	B	E	32.310	29.615	5.1	2.55	20.08	
344	B	E	32.199	29.459	6.0	2.50	20.28	
346	B	E	32.361	29.472	4.1	2.79	19.80	
98	B	E	32.195	29.420	5.6	2.57	20.06	

Operated by: John Tallarico	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bolton	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
653	B	E	32.150	29.406	5.7	2.52	20.24	
416	B	E	32.306	29.566	4.7	2.51	20.20	
612	B	E	32.316	29.586	5.6	2.63	19.90	
694	B	E	32.467	29.853	6.6	2.55	20.18	
620	B	E	32.180	29.290	6.5	2.52	19.48	
564	B	E	32.401	29.646	6.0	2.68	19.78	
287	B	E	32.268	29.531	5.6	2.47	20.26	
681	B	E	32.189	29.308	5.5	2.66	19.84	
890	B	E	32.280	29.554	/	2.55	20.06	no data due to instrument/ operator error DS 5/11/00
342	B	E	32.218	29.490	6.1	2.56	19.84	

Operated by: John Tallarico	Date: 11/11/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bilka	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
207	B	E	32.117	29.280	4.4	2.70	19.66	
68	B	E	32.233	29.542	5.4	2.51	19.98	
725	B	E	32.446	29.698	5.0	2.71	20.34	
492	B	E	32.279	29.491	4.9	2.57	19.82	
816	B	E	32.316	29.557	6.0	2.65	20.14	
134	B	E	32.426	29.698	6.0	2.53	20.14	
136	B	E	32.286	29.565	5.9	2.44	20.14	
658	B	E	32.233	29.531	4.9	2.61	19.74	
41	B	E	32.265	29.483	5.5	2.69	20.22	
466	B	E	32.317	29.516	5.8	2.60	20.00	

Operated by: Lamonee Bullen	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soter	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lamonee Bullen	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
861	B	E	32.242	29.385	4.4	3.71	19.80	
313	B	E	32.380	29.598	6.0	3.52	19.94	
702	B	E	32.168	29.290	5.7	2.81	19.72	
155	B	E	32.175	29.424	4.7	2.40	20.00	
409	B	E	32.129	29.310	6.1	2.72	20.24	
822	B	E	32.335	29.620	6.1	2.62	19.96	
362	B	E	32.078	29.344	5.8	2.70	19.64	
862	B	E	32.212	29.490	6.0	2.42	19.80	
945	B	E	32.247	29.510	5.2	2.65	19.96	
170	B	E	32.247	29.408	5.5	2.44	20.02	

Operated by: John Tallarico	Date: 11/Mar/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Butler	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
109	B	E	32.481	29.726	6.1	4.41	19.98	
563	B	E	32.221	29.481	6.4	3.07	19.50	
935	B	E	32.294	29.542	4.8	2.56	20.02	
343	B	E	32.349	29.573	5.6	2.53	20.08	
794	B	E	32.307	29.615	6.2	2.40	19.94	
286	B	E	32.305	29.587	6.1	2.72	20.04	
97	B	E	32.183	29.321	5.7	2.65	20.22	
701	B	E	32.239	29.467	6.2	2.45	20.00	
376	B	E	32.177	29.362	6.0	2.46	19.52	
545	B	E	32.120	29.313	6.0	2.63	19.32	

Operated by: Lawrence Bullen	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
87	B	E	32.124	29.258	6.6	3.97	20.16	
889	B	E	32.316	29.459	6.7	2.64	19.82	
375	B	E	32.334	29.594	5.9	2.53	19.82	
960	B	E	32.481	29.746	5.8	2.56	19.78	
571	B	E	32.239	29.527	5.8	2.43	20.06	
167	B	E	32.307	29.573	5.9	2.56	20.06	
978	B	E	32.242	29.348	6.4	2.53	18.94	
176	B	E	32.469	29.733	5.8	2.66	20.04	
16	B	E	32.131	29.282	5.7	2.70	20.20	
13	B	E	32.323	29.461	6.1	2.63	19.84	

Operated by: Lawrence Bullen	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
49	B	E	32.296	29.555	5.7	2.59	20.06	
496	B	E	32.267	29.539	6.1	2.58	19.82	
860	B	E	32.216	29.497	5/11/00 WN ~~5.8~~ 5.7	2.51	20.20	
883	B	E	32.185	29.407	6.1	2.47	19.52	
420	B	E	32.300	29.466	6.1	2.66	20.24	
522	B	E	32.350	29.597	5.5	2.49	19.50	
715	B	E	32.241	29.519	5.4	2.55	20.14	
351	B	E	32.202	29.464	5.4	2.66	20.06	
291	B	E	32.178	29.426	6.5	2.49	19.96	
1	B	E	32.257	29.501	5.8	2.55	20.04	

Operated by: Lawrence Bullen	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soter	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/12/00

WN = wrong number

Autoinjector Functionality Testing

Study Number: G472506B

Comments continued, listed by serial number (initial and date each comment)

Operated by: na	Date: na	Data Recorded/Witnessed by: na	Date: na
Reviewed by: na	Date: na	Data Key Entered by: na	Date: na

Autoinjector Functionality Testing
Study Number: G472506B

Firing Force (FF)		Dispensed Volume Saline (DV)	
Method Followed:	Method No.31-00/Chemistry	Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Graphtec SR6312 Chart Recorder	Instrument Used:	Scaltec Digital Scale SBA41
ID/Serial Number:	LN462090	ID/Serial Number:	C17157
		Solution Density:	1.0046 g/ml LB 5/31/00

Time of Delivery (TD)/Speed of Delivery		Needle Length (NL)	
Method Followed:	Method No.31-00/Chemistry	Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Fluke 1953A Counter Timer	Instrument Used:	Starrett Digital Indicator F2730-1
ID/Serial Number:	LN244927	ID/Serial Number:	000076025

Physical Condition of the Auto Injector, to include packaging material i.e. intact, etc.)	Method Followed: Method No.31-00/Chemistry

Setup Performed by:	Lawrence Bullen	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Code Definitions:

Package Condition Codes:

A = End of package has been opened and then taped closed to prevent device from falling out of package.
B = Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe.
C = Package is punctured exposing device.
D = In relatively good condition, no significant package damage.

Device Condition Codes:

E = No apparent damage.
F = Some damage observed, see Comments column. Additional comments may be found on the last page of this series of tests. Comments are listed by Serial Number.

Codes for Any Additional Comments (Initial and Date)

Operated by: na	Date: na	Data Recorded/Witnessed by: na	Date: na
Reviewed by: na	Date: na	Data Key Entered by: na	Date: na

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
92	B	E	32.413	29.678	5.9	2.60	20.38	
5	B	E	32.182	29.457	5.7	2.48	20.20	
954	B	E	32.275	29.533	6.7	2.41	19.90	
226	B	E	32.150	29.429	5.7	2.46	19.80	
504	B	E	32.358	29.618	5.9	2.46	19.96	
381	B	E	32.218	29.479	5.5	2.58	19.68	
310	B	E	32.307	29.578	5.0	2.54	20.00	
43	B	E	32.183	29.433	4.4	2.65	20.32	
663	B	E	32.360	29.601	5.9	2.50	19.94	
285	B	E	32.406	29.680	5.8	2.60	19.80	

Operated by: John Tallarico	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
589	B	E	32.124	29.377	5.9	4.10	20.02	
307	B	E	32.193	29.457	5.4	2.47	19.88	
737	B	E	32.266	29.493	6.0	2.66	20.28	
202	B	E	32.452	29.721	6.4	2.57	19.70	
290	B	E	32.161	29.421	5.1	2.73	20.14	
999	B	E	32.244	29.510	6.3	2.56	20.00	
568	B	E	32.218	29.466	5.7	2.55	19.82	
539	B	E	32.247	29.495	5.0 WN ZB ~~5.2~~ 5/16/00	2.69	19.90	
734	B	E	32.183	29.427	5.9	2.67	20.12	
931	B	E	32.122	29.369	6.0	2.43	20.26	

Operated by: John Tallarico	Date: 11/M24/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5-11-00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Laurena Bullar	Date: 5-11-00

WN: wrong Number
Verified with strip chart 5/31/00 ZB

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
102	B	E	32.250	29.496	5.9	/	19.82	no data due to instrument / operator error DS 5/11/00
187	B	E	32.151	29.400	6.1	3.18	20.04	
81	B	E	32.162	29.386	6.0	2.60	20.04	
967	B	E	32.412	29.677	5.0	2.64	20.14	
829	B	E	32.416	29.648	6.0	2.64	20.32	
34	B	E	32.154	29.427	6.3	2.47	20.36	
431	B	E	32.144	29.402	5.2	2.60	19.90	
991	B	E	32.265	29.399	6.4	2.91	19.98	
609	B	E	32.369	29.624	4.5	2.64	19.90	
64	B	E	32.361	29.629	6.5	2.54	20.28	

Operated by: John Talbucci	Date: 11/M24/2000	Data Recorded/Witnessed by: Diane Soter	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
27	B	E	32.227	29.489	5.7	2.58	20.02	
44	B	E	32.236	29.359	6.3	2.83	19.92	
12	B	E	32.359	29.589	4.7	2.65	20.00	
922	B	E	32.251	29.504	5.6	2.55	20.00	
669	B	E	32.269	29.496	6.1	2.55	19.56	
679	B	E	32.225	29.492	6.1	2.66	19.02	
600	B	E	32.306	29.588	5.6	2.45	20.06	
325	B	E	32.226	29.473	6.1	2.46	20.06	
477	B	E	32.313	29.476	6.2	2.68	20.20	
595	B	E	32.395	29.655	6.1	2.45	20.06	

Operated by: John Fallarco	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
998	B	E	32.276	29.399	6.1	2.89	19.74	
666	B	E	32.319	29.621	6.3	3.58	19.32	
834	B	E	32.127	29.517	5.5	2.38	20.16	
661	B	E	32.282	29.541	5.1	2.62	19.88	
835	B	E	32.238	29.476	6.1	2.45	19.86	
885	B	E	32.466	29.674	5.9	2.49	19.88	
470	B	E	32.287	29.499	6.3	2.60	19.96	
227	B	E	32.365	29.530	5.6	2.74	19.84	
149	B	E	32.326	29.569	5.5	2.66	19.18	
443	B	E	32.182	29.328	5.9	2.65	20.12	

Operated by: Lamonna Bullen	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lamonna Bullen	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
728	B	E	32.323	29.594	6.1	3.40	20.28	
145	B	E	32.267	29.562	6.3	4.72	19.48	
929	B	E	32.330	29.627	6.4	2.45	20.00	
201	B	E	32.269	29.486	6.3	2.72	20.22	
801	B	E	32.186	29.355	5.6	2.78	19.60	
693	B	E	32.276	29.576	5.2	2.48	19.88	
408	B	E	32.339	29.573	5.3	2.53	19.74	
410	B	E	32.259	29.493	6.5	2.53	20.14	
920	B	E	32.286	29.609	4.2	2.52	19.38	
197	B	E	32.482	29.744	6.0	2.40	20.04	

Operated by: John Tallarico	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
19	B	E	32.241	29.513	5.9	2.66	20.08	
299	B	E	32.215	29.431	5.6	2.70	20.32	
411	B	E	32.292	29.524	5.6	2.70	19.98	
705	B	E	32.252	29.520	5.4	2.60	20.36	
352	B	E	32.288	29.550	5.6	2.52	20.00	
667	B	E	32.218	29.484	5.7	2.49	19.96	
15	B	E	32.283	29.560	6.1	2.52	20.08	
685	B	E	32.165	29.379	5.7	2.76	20.10	
966	B	E	32.318	29.572	5.9	2.63	19.98	
278	B	E	32.308	29.562	5.9	2.51	19.96	

Operated by: Lawrence Ballon	Date: 5/11/00	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Ballon	Date: 5/11/00

Form No. Chemstry MREF-046-00 (Registered 5/10/00)

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
550	B	E	32.189	29.328	5.8	2.46	19.62	
321	B	E	32.213	29.430	5.5	2.57	19.98	
84	B	E	32.403	29.650	6.2	2.55	19.66	
246	B	E	32.478	29.690	5.7	2.52	19.30	
293	B	E	32.132	29.396	6.2	2.57	19.88	
181	B	E	32.216	29.474	5.6	2.49	20.34	
222	B	E	32.316	29.586	5.1	2.61	19.82	
485	B	E	32.266	29.516	5.6	2.48	19.58	
282	B	E	32.141	29.377	5.8	2.71	20.06	
634	B	E	32.352	29.654	5.8	2.53	20.30	

Operated by: John Tallarico	Date: 11/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/11/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullock	Date: 5/11/00

Autoinjector Functionality Testing

Study Number: G472506B

Comments continued, listed by serial number (initial and date each comment)

Operated by: na	Date: na	Data Recorded/Witnessed by: na	Date: na
Reviewed by: na	Date: na	Data Key Entered by: na	Date: na

Autoinjector Functionality Testing
Study Number: G472506B

Firing Force (FF)		Dispensed Volume Saline (DV)	
Method Followed:	Method No.31-00/Chemistry	Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Graphtec SR6312 Chart Recorder	Instrument Used:	Scaltec Digital Scale SBA41
ID/Serial Number:	LN462090	ID/Serial Number:	C17157
		Solution Density:	1.0046 g/mL

Time of Delivery (TD)/Speed of Delivery		Needle Length (NL)	
Method Followed:	Method No.31-00/Chemistry	Method Followed:	Method No.31-00/Chemistry
Instrument Used:	Fluke 1953A Counter Timer	Instrument Used:	Starrett Digital Indicator F2730-1
ID/Serial Number:	LN244927	ID/Serial Number:	000076025

Physical Condition of the Auto Injector, to include packaging material i.e. intact, etc.)	Method Followed: Method No.31-00/Chemistry

Setup Performed by:	Lawrence Bullen	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Code Definitions:

Package Condition Codes:

A = End of package has been opened and then taped closed to prevent device from falling out of package.
B = Clear outside layer has peeled away from the brown inside layer of package. Condition ranges from moderate to severe.
C = Package is punctured exposing device.
D = In relatively good condition, no significant package damage.

Device Condition Codes:

E = No apparent damage.
F = Some damage observed, see Comments column. Additional comments may be found on the last page of this series of tests. Comments are listed by Serial Number.

Codes for Any Additional Comments (Initial and Date)

Operated by: na	Date: na	Data Recorded/Witnessed by: na	Date: na
Reviewed by: na	Date: na	Data Key Entered by: na	Date: na

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
137	B	E	32.359	29.490	4.3 WN ~~6.3~~ 5/31/00	2.61	19.72	
353	B	E	32.280	29.651	6.1	2.43	19.86	
30	B	E	32.176	29.452	6.2	2.66	20.18	
876	B	E	32.222	29.357	4.1	2.81	20.26	
654	B	E	32.152	29.441	5.1	2.64	20.32	
824	B	E	32.197	29.419	6.1	2.59	19.90	
925	B	E	32.304	29.576	5.3	2.50	20.16	
1100	A	E	32.227	29.490	6.3	2.26	20.14	
1157	A	E	32.147	29.400	6.0	2.55	19.80	
1114	A	E	32.071	29.350	5.2	2.44	19.84	

Operated by: John Tallarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/12/00

WN: Wrong Number
Verified with strip chart JB 5/31/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
1137	A	E	32.149	29.409	6.0	2.57	19.80	
1191	A	E	32.394	29.659	4.6	2.60	19.84	
1183	A	E	32.281	29.499	6.3	2.59	20.08	
1042	A	E	32.145	29.421	6.0	2.35	19.54	
1028	A	E	32.258	29.538	6.7	2.54	19.78	
1141	A	E	32.174	29.547	5.0	2.48	19.92	
1007	A	E	32.240	29.489	5.8	2.39	20.16	
1044	A	E	32.208	29.482	6.4	2.40	20.20	
1012	A	E	32.303	29.618	6.4	2.51	19.52	
1047	A	E	32.222	29.477	5.8	2.65	20.12	

Operated by: John Tallarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
1151	A	E	32.429	29.684	5.0	2.54	20.26	
1017	A	E	32.181	29.470	5.8	2.57	19.96	
1142	A	E	32.340	29.574	5.7	2.52	19.90	
1072	A	E	32.042	29.281	6.5	2.49	19.66	
1068	A	E	32.237	29.521	5.8	2.88	19.94	
1192	A	E	32.329	29.608	6.5	2.50	19.96	
1041	A	E	32.042 WN ~~32.08~~ QB 5/12/00	29.291	5.4	3.33	20.06	
1029	A	E	32.374	29.657	4.9	4.37	19.82	
1079	A	E	32.266	29.520	WN 4.7 QB ~~5.2~~ 5/16/00	3.10	19.86	
1059	A	E	32.221	29.535	4.7	2.64	19.96	

Operated by: John Tallarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/12/00

WN: wrong Number
Verified with strip chart QB 5/31/00

wn = wrong number

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
1187	A	E	32.237	29.479	5.8	2.43	20.06	
1067	A	E	32.170	29.420	5.3	2.66	19.88	
1146	A	E	32.179	29.423	5.9	2.66	19.78	
1045	A	E	32.289	29.531	6.8	2.50	19.48	
1051	A	E	32.386	29.703	6.0	2.44	20.10	
1163	A	E	32.136	29.398	6.0	2.54	19.94	
1013	A	E	32.206	29.481	5.7	2.56	19.66	
1036	A	E	32.071	29.331	5.7	2.62	20.04	
1147	A	E	32.090	29.341	6.3	2.57	19.72	
1062	A	E	32.251	29.507	6.0	2.48	19.86	

Operated by: Lawrence Bullen	Date: 5/12/00	Data Recorded/Witnessed by: Diane Soter	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullen	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
1182	A	E	32.174	29.427	5.5	2.48	19.84	
1019	A	E	32.194	29.441	5.0	2.57	19.94	
1016	A	E	32.317	29.576	5.7	2.56	20.10	
1002	A	E	32.114	29.393	5.7	2.48	20.48	
1194	A	E	32.121	29.407	5.2	2.66	20.28	
1144	A	E	32.245	29.472	5.5	2.55	20.04	
1167	A	E	32.179	29.437	5.0	2.79	19.76	
1179	A	E	32.255	29.488	5.8	2.39	20.20	
1055	A	E	32.287	29.529	6.2	2.49	19.36	
1056	A	E	32.139	29.448	5.7	2.68	20.06	

Operated by: John Tallarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Butler	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
1128	A	E	32.103	29.393	6.7	3.22	20.10	
1040	A	E	32.261	29.549	6.1	3.61	19.44	
1074	A	E	32.118	29.398	7.0	2.53	19.42	
1166	A	E	32.273	29.540	4.4	2.56	20.22	
1057	A	E	32.343	29.562	6.3	2.40	19.96	
1159	A	E	32.399	29.691	6.0	2.56	19.72	
1153	A	E	32.271	29.606	5.7	2.55	19.56	
1113	A	E	32.164	29.467	6.8	2.43	19.70	
854	C	E	32.358	29.647	5.2	2.59	19.96	
269	C	E	32.291	29.573	5.4	2.52	19.82	

Operated by: John Tallarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Bullar	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
77	C	E	32.267	29.520	5.1	2.68	19.76	
736	C	E	32.312	29.540	5.8	2.67	20.20	
36	C	E	32.344	29.595	6.1	2.59	19.40	
1024	C	E	32.242	29.534	5.8	2.62	19.72	
918	D	E	32.238	29.497	WN 5.0 2B ~~5.3~~ 5/16/00	2.37	19.94	
31	D	E	32.135	29.389	6.1	2.61	20.04	
304	D	E	32.340	29.636	5.9	2.49	19.98	
288	D	E	32.394	29.638	5.7	2.47	19.80	
902	B	E	32.268	29.544	5.5	2.56	19.88	
784	B	E	32.310	29.570	6.5	2.65	19.66	

Operated by: John Talbarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Laurence Butler	Date: 5/12/00

WN: Wrong Number
Verified with strip chart 5/31/00 2B

Autoinjector Functionality Testing

Study Number: G472506B

Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	Comments (Initial and Date)
175	B	E	32.321	29.576	5.3	2.64	19.96	

Operated by: John Tallarico	Date: 12/May/2000	Data Recorded/Witnessed by: Diane Soto	Date: 5/12/00
Reviewed by:	Date: 5/12/00	Data Key Entered by: Lawrence Butler	Date: 5/12/00

Autoinjector Functionality Testing

Study Number: G472506B

Comments continued, listed by serial number (initial and date each comment)

Operated by: na	Date: na	Data Recorded/Witnessed by: na	Date: na
Reviewed by: na	Date: na	Data Key Entered by: na	Date: na

Appendix E. Summary Spreadsheet

Autoinjector Functionality Testing
Study Number: G472506B
Tests performed: 5/10/00 to 5/12/00

Solution Density 1.0046 g/mL

Sequence Number	Date	Data Sheet Page Number	Unit Serial Number	Package Condition Code	Device Condition Code	Initial Weight (g)	Final Weight (g)	FF - Firing Force (lbs)	TD - Time of Delivery (sec)	NL - Needle Length (mm)	VD - Volume Delivered = (Initial Weight - Final Weight)/Density mL
1	10-May-00	3 of 4	895	B	E	32.361	29.606	5.3	3.00	19.16	2.74
2	10-May-00	3 of 4	78	B	E	32.381	29.591	6.0	2.58	19.98	2.78
3	10-May-00	3 of 4	42	B	E	32.245	29.480	5.5	2.67	19.98	2.75
4	10-May-00	3 of 4	114	B	E	32.435	29.708	6.4	2.60	20.32	2.71
5	10-May-00	3 of 4	509	B	E	32.090	29.338	5.1	2.73	20.10	2.74
6	10-May-00	3 of 4	622	B	E	32.154	29.414	5.6	2.42	20.26	2.73
7	10-May-00	3 of 4	894	B	E	32.276	29.543	6.0	2.47	19.68	2.72
8	10-May-00	3 of 4	930	B	E	32.347	29.598	6.5	ND	19.90	2.74
9	11-May-00	3 of 11	92	B	E	32.413	29.678	5.9	2.60	20.38	2.72
10	11-May-00	3 of 11	5	B	E	32.182	29.457	5.7	2.48	20.20	2.71
11	11-May-00	3 of 11	954	B	E	32.275	29.533	6.7	2.41	19.90	2.73
12	11-May-00	3 of 11	226	B	E	32.150	29.429	5.7	2.46	19.80	2.71
13	11-May-00	3 of 11	504	B	E	32.358	29.618	5.9	2.46	19.96	2.73
14	11-May-00	3 of 11	381	B	E	32.218	29.479	5.5	2.58	19.68	2.73
15	11-May-00	3 of 11	310	B	E	32.307	29.578	5.0	2.54	20.00	2.72
16	11-May-00	3 of 11	43	B	E	32.183	29.433	4.4	2.65	20.32	2.74
17	11-May-00	3 of 11	663	B	E	32.360	29.601	5.9	2.50	19.94	2.75
18	11-May-00	3 of 11	285	B	E	32.406	29.680	5.8	2.60	19.80	2.71
19	11-May-00	4 of 11	589	B	E	32.124	29.377	5.9	4.10	20.02	2.73
20	11-May-00	4 of 11	307	B	E	32.193	29.457	5.4	2.47	19.88	2.72
21	11-May-00	4 of 11	737	B	E	32.266	29.493	6.0	2.66	20.28	2.76
22	11-May-00	4 of 11	202	B	E	32.452	29.721	6.4	2.57	19.70	2.72
23	11-May-00	4 of 11	290	B	E	32.161	29.421	5.1	2.73	20.14	2.73
24	11-May-00	4 of 11	999	B	E	32.244	29.510	6.3	2.56	20.00	2.72
25	11-May-00	4 of 11	568	B	E	32.218	29.466	5.7	2.55	19.82	2.74
26	11-May-00	4 of 11	539	B	E	32.247	29.495	5.0	2.69	19.90	2.74
27	11-May-00	4 of 11	734	B	E	32.183	29.427	5.9	2.67	20.12	2.74
28	11-May-00	4 of 11	931	B	E	32.122	29.369	6.0	2.43	20.26	2.74
29	11-May-00	5 of 11	102	B	E	32.250	29.496	5.9	ND	19.82	2.74
30	11-May-00	5 of 11	187	B	E	32.151	29.400	6.1	3.18	20.04	2.74
31	11-May-00	5 of 11	81	B	E	32.162	29.386	6.0	2.60	20.04	2.76
32	11-May-00	5 of 11	967	B	E	32.412	29.677	5.0	2.64	20.14	2.72
33	11-May-00	5 of 11	829	B	E	32.416	29.648	6.0	2.64	20.32	2.76
34	11-May-00	5 of 11	34	B	E	32.154	29.427	6.3	2.47	20.36	2.71
35	11-May-00	5 of 11	431	B	E	32.144	29.402	5.2	2.60	19.90	2.73
36	11-May-00	5 of 11	991	B	E	32.265	29.399	6.4	2.91	19.98	2.85
37	11-May-00	5 of 11	609	B	E	32.369	29.624	4.5	2.64	19.90	2.73
38	11-May-00	5 of 11	64	B	E	32.361	29.629	6.5	2.54	20.28	2.72
39	11-May-00	6 of 11	27	B	E	32.227	29.489	5.7	2.58	20.02	2.73
40	11-May-00	6 of 11	44	B	E	32.236	29.359	6.3	2.83	19.92	2.86
41	11-May-00	6 of 11	12	B	E	32.359	29.589	4.7	2.65	20.00	2.76
42	11-May-00	6 of 11	922	B	E	32.251	29.504	5.6	2.55	20.00	2.73
43	11-May-00	6 of 11	669	B	E	32.269	29.496	6.1	2.55	19.56	2.76
44	11-May-00	6 of 11	679	B	E	32.225	29.492	6.1	2.66	19.02	2.72
45	11-May-00	6 of 11	600	B	E	32.306	29.588	5.6	2.45	20.06	2.71
46	11-May-00	6 of 11	325	B	E	32.226	29.473	6.1	2.46	20.06	2.74
47	11-May-00	6 of 11	477	B	E	32.313	29.476	6.2	2.68	20.20	2.82

ND = no data due to instrument/operator error

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48	11-May-00	6 of 11	595	B	E	32.395	29.655	6.1	2.45	20.06	2.73
49	11-May-00	7 of 11	998	B	E	32.276	29.399	6.1	2.89	19.74	2.86
50	11-May-00	7 of 11	666	B	E	32.319	29.621	6.3	3.58	19.32	2.69
51	11-May-00	7 of 11	834	B	E	32.127	29.517	5.5	2.38	20.16	2.60
52	11-May-00	7 of 11	661	B	E	32.282	29.541	5.1	2.62	19.88	2.73
53	11-May-00	7 of 11	835	B	E	32.238	29.476	6.1	2.45	19.86	2.75
54	11-May-00	7 of 11	885	B	E	32.466	29.674	5.9	2.49	19.88	2.78
55	11-May-00	7 of 11	470	B	E	32.287	29.499	6.3	2.60	19.96	2.78
56	11-May-00	7 of 11	227	B	E	32.365	29.530	5.6	2.74	19.84	2.82
57	11-May-00	7 of 11	149	B	E	32.326	29.569	5.5	2.66	19.18	2.74
58	11-May-00	7 of 11	443	B	E	32.182	29.328	5.9	2.65	20.12	2.84
59	11-May-00	8 of 11	728	B	E	32.323	29.594	6.1	3.40	20.28	2.72
60	11-May-00	8 of 11	145	B	E	32.267	29.562	6.3	4.72	19.48	2.69
61	11-May-00	8 of 11	929	B	E	32.330	29.627	6.4	2.45	20.00	2.69
62	11-May-00	8 of 11	201	B	E	32.269	29.486	6.3	2.72	20.22	2.77
63	11-May-00	8 of 11	801	B	E	32.186	29.355	5.6	2.78	19.60	2.82
64	11-May-00	8 of 11	693	B	E	32.276	29.576	5.2	2.48	19.88	2.69
65	11-May-00	8 of 11	408	B	E	32.339	29.573	5.3	2.53	19.74	2.75
66	11-May-00	8 of 11	410	B	E	32.259	29.493	6.5	2.53	20.14	2.75
67	11-May-00	8 of 11	920	B	E	32.286	29.609	4.2	2.52	19.38	2.66
68	11-May-00	8 of 11	197	B	E	32.482	29.744	6.0	2.40	20.04	2.73
69	11-May-00	9 of 11	19	B	E	32.241	29.513	5.9	2.66	20.08	2.72
70	11-May-00	9 of 11	299	B	E	32.215	29.431	5.6	2.70	20.32	2.77
71	11-May-00	9 of 11	411	B	E	32.292	29.524	5.6	2.70	19.98	2.76
72	11-May-00	9 of 11	705	B	E	32.252	29.520	5.4	2.60	20.36	2.72
73	11-May-00	9 of 11	352	B	E	32.288	29.550	5.6	2.52	20.00	2.73
74	11-May-00	9 of 11	667	B	E	32.218	29.484	5.7	2.49	19.96	2.72
75	11-May-00	9 of 11	15	B	E	32.283	29.560	6.1	2.52	20.08	2.71
76	11-May-00	9 of 11	685	B	E	32.165	29.379	5.7	2.76	20.10	2.77
77	11-May-00	9 of 11	966	B	E	32.318	29.572	5.9	2.63	19.98	2.73
78	11-May-00	9 of 11	278	B	E	32.308	29.562	5.9	2.51	19.96	2.73
79	11-May-00	10 of 11	550	B	E	32.189	29.328	5.8	2.46	19.62	2.85
80	11-May-00	10 of 11	321	B	E	32.213	29.430	5.5	2.57	19.98	2.77
81	11-May-00	10 of 11	84	B	E	32.403	29.650	6.2	2.55	19.66	2.74
82	11-May-00	10 of 11	246	B	E	32.478	29.690	5.7	2.52	19.30	2.78
83	11-May-00	10 of 11	293	B	E	32.132	29.396	6.2	2.57	19.88	2.72
84	11-May-00	10 of 11	181	B	E	32.216	29.474	5.6	2.49	20.34	2.73
85	11-May-00	10 of 11	222	B	E	32.316	29.586	5.1	2.61	19.82	2.72
86	11-May-00	10 of 11	485	B	E	32.266	29.516	5.6	2.48	19.58	2.74
87	11-May-00	10 of 11	282	B	E	32.141	29.377	5.8	2.71	20.06	2.75
88	11-May-00	10 of 11	634	B	E	32.352	29.654	5.8	2.53	20.30	2.69
89	11-May-00	3 of 17	254	B	E	32.252	29.511	6.0	2.46	20.12	2.73
90	11-May-00	3 of 17	292	B	E	32.404	29.666	5.1	2.58	20.08	2.73
91	11-May-00	3 of 17	279	B	E	32.400	29.570	6.3	2.60	19.72	2.82
92	11-May-00	3 of 17	228	B	E	32.024	29.300	5.3	2.57	19.98	2.71
93	11-May-00	3 of 17	866	B	E	32.473	29.744	5.1	2.61	19.92	2.72
94	11-May-00	3 of 17	905	B	E	32.282	29.535	5.9	2.29	19.66	2.73
95	11-May-00	3 of 17	797	B	E	32.194	29.435	5.1	2.63	20.08	2.75
96	11-May-00	3 of 17	722	B	E	32.436	29.708	5.5	2.54	19.76	2.72
97	11-May-00	3 of 17	334	B	E	32.141	29.304	6.2	2.58	20.20	2.82
98	11-May-00	3 of 17	427	B	E	32.422	29.725	5.3	2.64	20.40	2.68
99	11-May-00	4 of 17	37	B	E	32.354	29.449	5.5	2.50	19.84	2.89
100	11-May-00	4 of 17	538	B	E	32.208	29.493	5.7	2.45	19.78	2.70
101	11-May-00	4 of 17	853	B	E	32.294	29.553	4.5	2.58	19.86	2.73
102	11-May-00	4 of 17	284	B	E	32.358	29.592	6.0	2.59	20.00	2.75
103	11-May-00	4 of 17	447	B	E	32.234	29.532	6.0	2.58	19.18	2.69
104	11-May-00	4 of 17	645	B	E	32.207	29.416	5.9	3.03	20.12	2.78
105	11-May-00	4 of 17	315	B	E	32.214	29.402	5.8	2.63	19.86	2.80
106	11-May-00	4 of 17	819	B	E	32.416	29.675	5.7	2.51	20.18	2.73
107	11-May-00	4 of 17	852	B	E	32.174	29.456	5.7	2.47	20.04	2.71

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108	11-May-00	4 of 17	455	B	E	32.509	29.803	5.8	2.56	20.04	2.69
109	11-May-00	5 of 17	300	B	E	32.307	29.471	5.6	2.84	19.86	2.82
110	11-May-00	5 of 17	757	B	E	32.266	29.509	5.7	2.50	20.20	2.74
111	11-May-00	5 of 17	341	B	E	32.208	29.498	6.1	2.53	20.26	2.70
112	11-May-00	5 of 17	752	B	E	32.266	29.574	6.2	2.50	20.38	2.68
113	11-May-00	5 of 17	404	B	E	32.159	29.429	5.5	2.43	19.96	2.72
114	11-May-00	5 of 17	73	B	E	32.259	29.504	5.7	2.66	20.10	2.74
115	11-May-00	5 of 17	941	B	E	32.418	29.567	6.0	2.56	20.12	2.84
116	11-May-00	5 of 17	735	B	E	32.226	29.514	6.0	2.41	20.16	2.70
117	11-May-00	5 of 17	390	B	E	32.291	29.554	5.1	2.58	19.90	2.72
118	11-May-00	5 of 17	361	B	E	32.211	29.494	6.0	2.63	20.14	2.70
119	11-May-00	6 of 17	82	B	E	32.405	29.749	4.8	4.14	19.46	2.64
120	11-May-00	6 of 17	171	B	E	32.261	29.544	4.6	2.61	19.98	2.70
121	11-May-00	6 of 17	825	B	E	32.290	29.525	5.8	2.66	19.72	2.75
122	11-May-00	6 of 17	386	B	E	32.423	29.693	5.1	2.62	20.14	2.72
123	11-May-00	6 of 17	412	C	E	32.427	29.563	5.8	2.47	20.02	2.85
124	11-May-00	6 of 17	898	B	E	32.301	29.445	6.2	2.64	19.78	2.84
125	11-May-00	6 of 17	442	B	E	32.270	29.534	5.6	2.60	20.28	2.72
126	11-May-00	6 of 17	789	B	E	32.348	29.600	5.7	2.52	20.24	2.74
127	11-May-00	6 of 17	131	B	E	32.194	29.458	4.8	2.31	20.24	2.72
128	11-May-00	6 of 17	448	B	E	32.361	29.495	6.0	2.72	20.20	2.85
129	11-May-00	7 of 17	972	B	E	32.293	29.542	5.7	2.70	19.64	2.74
130	11-May-00	7 of 17	314	B	E	32.290	29.402	5.7	2.62	19.14	2.87
131	11-May-00	7 of 17	276	B	E	32.242	29.563	6.2	2.47	20.02	2.67
132	11-May-00	7 of 17	614	B	E	32.183	29.444	5.4	2.63	19.70	2.73
133	11-May-00	7 of 17	574	B	E	32.288	29.540	6.1	2.46	19.96	2.74
134	11-May-00	7 of 17	981	B	E	32.249	29.529	6.0	2.57	19.52	2.71
135	11-May-00	7 of 17	242	B	E	32.324	29.644	5.5	2.37	19.54	2.67
136	11-May-00	7 of 17	405	B	E	32.224	29.467	6.4	2.60	19.96	2.74
137	11-May-00	7 of 17	93	B	E	32.298	29.549	6.1	2.39	20.18	2.74
138	11-May-00	7 of 17	113	B	E	32.370	29.594	5.7	2.46	19.58	2.76
139	11-May-00	8 of 17	303	B	E	32.128	29.395	5.5	3.24	20.06	2.72
140	11-May-00	8 of 17	186	B	E	32.242	29.506	6.4	2.58	19.94	2.72
141	11-May-00	8 of 17	212	B	E	32.224	29.497	5.4	2.57	19.98	2.71
142	11-May-00	8 of 17	850	B	E	32.157	29.441	5.0	2.41	20.00	2.70
143	11-May-00	8 of 17	280	B	E	32.168	29.434	5.7	2.50	19.96	2.72
144	11-May-00	8 of 17	29	B	E	32.477	29.796	5.6	2.56	20.06	2.67
145	11-May-00	8 of 17	324	B	E	32.209	29.417	4.6	2.65	19.66	2.78
146	11-May-00	8 of 17	66	B	E	32.215	29.467	5.4	2.60	19.54	2.74
147	11-May-00	8 of 17	506	B	E	32.312	29.570	5.3	2.58	20.20	2.73
148	11-May-00	8 of 17	91	B	E	32.526	29.791	5.3	2.58	20.34	2.72
149	11-May-00	9 of 17	273	B	E	32.143	29.299	5.8	2.86	19.84	2.83
150	11-May-00	9 of 17	823	B	E	32.346	29.604	3.8	2.55	19.88	2.73
151	11-May-00	9 of 17	368	B	E	32.234	29.519	5.9	2.43	19.96	2.70
152	11-May-00	9 of 17	463	B	E	32.289	29.550	5.3	2.57	19.60	2.73
153	11-May-00	9 of 17	897	B	E	32.396	29.674	5.9	2.32	19.98	2.71
154	11-May-00	9 of 17	320	B	E	32.193	29.429	5.4	2.63	19.84	2.75
155	11-May-00	9 of 17	252	B	E	32.336	29.520	6.3	2.55	19.82	2.80
156	11-May-00	9 of 17	301	B	E	32.387	29.656	5.1	2.56	20.14	2.72
157	11-May-00	9 of 17	882	B	E	32.264	29.382	6.2	2.71	19.92	2.87
158	11-May-00	9 of 17	686	B	E	32.359	29.613	5.4	2.53	20.36	2.73
159	11-May-00	10 of 17	957	B	E	32.292	29.590	5.7	3.74	20.36	2.69
160	11-May-00	10 of 17	621	B	E	32.108	29.379	5.3	3.06	19.60	2.72
161	11-May-00	10 of 17	468	B	E	32.195	29.470	5.2	2.67	19.82	2.71
162	11-May-00	10 of 17	751	B	E	32.345	29.611	5.6	2.63	19.44	2.72
163	11-May-00	10 of 17	337	B	E	32.322	29.506	5.6	2.76	19.74	2.80
164	11-May-00	10 of 17	814	B	E	32.202	29.487	5.8	2.60	19.74	2.70
165	11-May-00	10 of 17	336	B	E	32.310	29.615	5.1	2.55	20.08	2.68
166	11-May-00	10 of 17	344	B	E	32.199	29.459	6.0	2.50	20.28	2.73
167	11-May-00	10 of 17	346	B	E	32.361	29.472	4.1	2.79	19.80	2.88

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168	11-May-00	10 of 17	98	B	E	32.195	29.420	5.6	2.57	20.06	2.76
169	11-May-00	11 of 17	653	B	E	32.150	29.406	5.7	2.52	20.24	2.73
170	11-May-00	11 of 17	416	B	E	32.306	29.566	4.7	2.51	20.20	2.73
171	11-May-00	11 of 17	612	B	E	32.316	29.586	5.6	2.63	19.90	2.72
172	11-May-00	11 of 17	694	B	E	32.467	29.853	6.6	2.55	20.18	2.60
173	11-May-00	11 of 17	620	B	E	32.180	29.290	6.5	2.52	19.48	2.88
174	11-May-00	11 of 17	564	B	E	32.401	29.646	6.0	2.68	19.78	2.74
175	11-May-00	11 of 17	287	B	E	32.268	29.531	5.6	2.47	20.26	2.72
176	11-May-00	11 of 17	681	B	E	32.189	29.308	5.5	2.66	19.84	2.87
177	11-May-00	11 of 17	890	B	E	32.280	29.554	ND	2.55	20.06	2.71
178	11-May-00	11 of 17	342	B	E	32.218	29.490	6.1	2.56	19.84	2.72
179	11-May-00	12 of 17	207	B	E	32.117	29.280	4.4	2.70	19.66	2.82
180	11-May-00	12 of 17	68	B	E	32.233	29.542	5.4	2.51	19.98	2.68
181	11-May-00	12 of 17	725	B	E	32.446	29.698	5.0	2.71	20.34	2.74
182	11-May-00	12 of 17	492	B	E	32.279	29.491	4.9	2.57	19.82	2.78
183	11-May-00	12 of 17	816	B	E	32.316	29.557	6.0	2.65	20.14	2.75
184	11-May-00	12 of 17	134	B	E	32.426	29.698	6.0	2.53	20.14	2.72
185	11-May-00	12 of 17	136	B	E	32.286	29.565	5.9	2.44	20.14	2.71
186	11-May-00	12 of 17	658	B	E	32.233	29.531	4.9	2.61	19.74	2.69
187	11-May-00	12 of 17	41	B	E	32.265	29.483	5.5	2.69	20.22	2.77
188	11-May-00	12 of 17	466	B	E	32.317	29.516	5.8	2.60	20.00	2.79
189	11-May-00	13 of 17	861	B	E	32.242	29.385	4.4	3.71	19.80	2.84
190	11-May-00	13 of 17	313	B	E	32.380	29.598	6.0	3.52	19.94	2.77
191	11-May-00	13 of 17	702	B	E	32.168	29.290	5.7	2.81	19.72	2.86
192	11-May-00	13 of 17	155	B	E	32.175	29.424	4.7	2.40	20.00	2.74
193	11-May-00	13 of 17	409	B	E	32.129	29.310	6.1	2.72	20.24	2.81
194	11-May-00	13 of 17	822	B	E	32.335	29.620	6.1	2.62	19.96	2.70
195	11-May-00	13 of 17	362	B	E	32.078	29.344	5.8	2.70	19.64	2.72
196	11-May-00	13 of 17	862	B	E	32.212	29.490	6.0	2.42	19.80	2.71
197	11-May-00	13 of 17	945	B	E	32.247	29.510	5.2	2.65	19.96	2.72
198	11-May-00	13 of 17	170	B	E	32.247	29.408	5.5	2.44	20.02	2.83
199	11-May-00	14 of 17	109	B	E	32.481	29.726	6.1	4.41	19.98	2.74
200	11-May-00	14 of 17	563	B	E	32.221	29.481	6.4	3.07	19.50	2.73
201	11-May-00	14 of 17	935	B	E	32.294	29.542	4.8	2.56	20.02	2.74
202	11-May-00	14 of 17	343	B	E	32.349	29.573	5.6	2.53	20.08	2.76
203	11-May-00	14 of 17	794	B	E	32.307	29.615	6.2	2.40	19.94	2.68
204	11-May-00	14 of 17	286	B	E	32.305	29.587	6.1	2.72	20.04	2.71
205	11-May-00	14 of 17	97	B	E	32.183	29.321	5.7	2.65	20.22	2.85
206	11-May-00	14 of 17	701	B	E	32.239	29.467	6.2	2.45	20.00	2.76
207	11-May-00	14 of 17	376	B	E	32.177	29.362	6.0	2.46	19.52	2.80
208	11-May-00	14 of 17	545	B	E	32.120	29.313	6.0	2.63	19.32	2.79
209	11-May-00	15 of 17	87	B	E	32.124	29.258	6.6	3.97	20.16	2.85
210	11-May-00	15 of 17	889	B	E	32.316	29.459	6.7	2.64	19.82	2.84
211	11-May-00	15 of 17	375	B	E	32.334	29.594	5.9	2.53	19.82	2.73
212	11-May-00	15 of 17	960	B	E	32.481	29.746	5.8	2.56	19.78	2.72
213	11-May-00	15 of 17	571	B	E	32.239	29.527	5.8	2.43	20.06	2.70
214	11-May-00	15 of 17	167	B	E	32.307	29.573	5.9	2.56	20.06	2.72
215	11-May-00	15 of 17	978	B	E	32.242	29.348	6.4	2.53	18.94	2.88
216	11-May-00	15 of 17	176	B	E	32.469	29.733	5.8	2.66	20.04	2.72
217	11-May-00	15 of 17	16	B	E	32.131	29.282	5.7	2.70	20.20	2.84
218	11-May-00	15 of 17	13	B	E	32.323	29.461	6.1	2.63	19.84	2.85
219	11-May-00	16 of 17	49	B	E	32.296	29.555	5.7	2.59	20.06	2.73
220	11-May-00	16 of 17	496	B	E	32.267	29.539	6.1	2.58	19.82	2.72
221	11-May-00	16 of 17	860	B	E	32.216	29.497	5.7	2.51	20.20	2.71
222	11-May-00	16 of 17	883	B	E	32.185	29.407	6.1	2.47	19.52	2.77
223	11-May-00	16 of 17	420	B	E	32.300	29.466	6.1	2.66	20.24	2.82
224	11-May-00	16 of 17	522	B	E	32.350	29.597	5.5	2.49	19.50	2.74
225	11-May-00	16 of 17	715	B	E	32.241	29.519	5.4	2.55	20.14	2.71
226	11-May-00	16 of 17	351	B	E	32.202	29.464	5.4	2.66	20.06	2.73
227	11-May-00	16 of 17	291	B	E	32.178	29.426	6.5	2.49	19.96	2.74

ND : No data due to instrument/operator error.

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228	11-May-00	16 of 17	1	B	E	32.257	29.501	5.8	2.55	20.04	2.74
229	12-May-00	3 of 11	137	B	E	32.359	29.490	4.3	2.61	19.72	2.86
230	12-May-00	3 of 11	353	B	E	32.280	29.651	6.1	2.43	19.86	2.62
231	12-May-00	3 of 11	30	B	E	32.176	29.452	6.2	2.66	20.18	2.71
232	12-May-00	3 of 11	876	B	E	32.222	29.357	4.1	2.81	20.26	2.85
233	12-May-00	3 of 11	654	B	E	32.152	29.441	5.1	2.64	20.32	2.70
234	12-May-00	3 of 11	824	B	E	32.197	29.419	6.1	2.59	19.90	2.77
235	12-May-00	3 of 11	925	B	E	32.304	29.576	5.3	2.50	20.16	2.72
236	12-May-00	3 of 11	1100	A	E	32.227	29.490	6.3	2.26	20.14	2.72
237	12-May-00	3 of 11	1157	A	E	32.147	29.400	6.0	2.55	19.80	2.73
238	12-May-00	3 of 11	1114	A	E	32.071	29.350	5.2	2.44	19.84	2.71
239	12-May-00	4 of 11	1137	A	E	32.149	29.409	6.0	2.57	19.80	2.73
240	12-May-00	4 of 11	1191	A	E	32.394	29.659	4.6	2.60	19.84	2.72
241	12-May-00	4 of 11	1183	A	E	32.281	29.499	6.3	2.59	20.08	2.77
242	12-May-00	4 of 11	1042	A	E	32.145	29.421	6.0	2.35	19.54	2.71
243	12-May-00	4 of 11	1028	A	E	32.258	29.538	6.7	2.54	19.78	2.71
244	12-May-00	4 of 11	1141	A	E	32.174	29.547	5.0	2.48	19.92	2.61
245	12-May-00	4 of 11	1007	A	E	32.240	29.489	5.8	2.39	20.16	2.74
246	12-May-00	4 of 11	1044	A	E	32.208	29.482	6.4	2.40	20.20	2.71
247	12-May-00	4 of 11	1012	A	E	32.303	29.618	6.4	2.51	19.52	2.67
248	12-May-00	4 of 11	1047	A	E	32.222	29.477	5.8	2.65	20.12	2.73
249	12-May-00	5 of 11	1151	A	E	32.429	29.684	5.0	2.54	20.26	2.73
250	12-May-00	5 of 11	1017	A	E	32.181	29.470	5.8	2.57	19.96	2.70
251	12-May-00	5 of 11	1142	A	E	32.340	29.574	5.7	2.52	19.90	2.75
252	12-May-00	5 of 11	1072	A	E	32.042	29.281	6.5	2.49	19.66	2.75
253	12-May-00	5 of 11	1068	A	E	32.237	29.521	5.8	2.88	19.94	2.70
254	12-May-00	5 of 11	1192	A	E	32.329	29.608	6.5	2.50	19.96	2.71
255	12-May-00	5 of 11	1041	A	E	32.042	29.291	5.4	3.33	20.06	2.74
256	12-May-00	5 of 11	1029	A	E	32.374	29.657	4.9	4.37	19.82	2.70
257	12-May-00	5 of 11	1079	A	E	32.266	29.520	4.7	3.10	19.86	2.73
258	12-May-00	5 of 11	1059	A	E	32.221	29.535	4.7	2.64	19.96	2.67
259	12-May-00	6 of 11	1187	A	E	32.237	29.479	5.8	2.43	20.06	2.75
260	12-May-00	6 of 11	1067	A	E	32.170	29.420	5.3	2.66	19.88	2.74
261	12-May-00	6 of 11	1146	A	E	32.179	29.423	5.9	2.66	19.78	2.74
262	12-May-00	6 of 11	1045	A	E	32.289	29.531	6.8	2.50	19.48	2.75
263	12-May-00	6 of 11	1051	A	E	32.386	29.703	6.0	2.44	20.10	2.67
264	12-May-00	6 of 11	1163	A	E	32.136	29.398	6.0	2.54	19.94	2.73
265	12-May-00	6 of 11	1013	A	E	32.206	29.481	5.7	2.56	19.66	2.71
266	12-May-00	6 of 11	1036	A	E	32.071	29.331	5.7	2.62	20.04	2.73
267	12-May-00	6 of 11	1147	A	E	32.090	29.341	6.3	2.57	19.72	2.74
268	12-May-00	6 of 11	1062	A	E	32.251	29.507	6.0	2.48	19.86	2.73
269	12-May-00	7 of 11	1182	A	E	32.174	29.427	5.5	2.48	19.84	2.73
270	12-May-00	7 of 11	1019	A	E	32.194	29.441	5.0	2.57	19.94	2.74
271	12-May-00	7 of 11	1016	A	E	32.317	29.576	5.7	2.56	20.10	2.73
272	12-May-00	7 of 11	1002	A	E	32.114	29.393	5.7	2.48	20.48	2.71
273	12-May-00	7 of 11	1194	A	E	32.121	29.407	5.2	2.66	20.28	2.70
274	12-May-00	7 of 11	1144	A	E	32.245	29.472	5.5	2.55	20.04	2.76
275	12-May-00	7 of 11	1167	A	E	32.179	29.437	5.0	2.79	19.76	2.73
276	12-May-00	7 of 11	1179	A	E	32.255	29.488	5.8	2.39	20.20	2.75
277	12-May-00	7 of 11	1055	A	E	32.287	29.529	6.2	2.49	19.36	2.75
278	12-May-00	7 of 11	1056	A	E	32.139	29.448	5.7	2.68	20.06	2.68
279	12-May-00	8 of 11	1128	A	E	32.103	29.393	6.7	3.22	20.10	2.70
280	12-May-00	8 of 11	1040	A	E	32.261	29.549	6.1	3.61	19.44	2.70
281	12-May-00	8 of 11	1074	A	E	32.118	29.398	7.0	2.53	19.42	2.71
282	12-May-00	8 of 11	1166	A	E	32.273	29.540	4.4	2.56	20.22	2.72
283	12-May-00	8 of 11	1057	A	E	32.343	29.562	6.3	2.40	19.96	2.77
284	12-May-00	8 of 11	1159	A	E	32.399	29.691	6.0	2.56	19.72	2.70
285	12-May-00	8 of 11	1153	A	E	32.271	29.606	5.7	2.55	19.56	2.65
286	12-May-00	8 of 11	1113	A	E	32.164	29.467	6.8	2.43	19.70	2.68
287	12-May-00	8 of 11	854	C	E	32.358	29.647	5.2	2.59	19.96	2.70

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288	12-May-00	8 of 11	269	C	E	32.291	29.573	5.4	2.52	19.82	2.71
289	12-May-00	9 of 11	77	C	E	32.267	29.520	5.1	2.68	19.76	2.73
290	12-May-00	9 of 11	736	C	E	32.312	29.540	5.8	2.67	20.20	2.76
291	12-May-00	9 of 11	36	C	E	32.344	29.595	6.1	2.59	19.40	2.74
292	12-May-00	9 of 11	1024	C	E	32.242	29.534	5.8	2.62	19.72	2.70
293	12-May-00	9 of 11	918	D	E	32.238	29.497	5.0	2.37	19.94	2.73
294	12-May-00	9 of 11	31	D	E	32.135	29.389	6.1	2.61	20.04	2.73
295	12-May-00	9 of 11	304	D	E	32.340	29.636	5.9	2.49	19.98	2.69
296	12-May-00	9 of 11	288	D	E	32.394	29.638	5.7	2.47	19.80	2.74
297	12-May-00	9 of 11	902	B	E	32.268	29.544	5.5	2.56	19.88	2.71
298	12-May-00	9 of 11	784	B	E	32.310	29.570	6.5	2.65	19.66	2.73
299	12-May-00	10 of 11	175	B	E	32.321	29.576	5.3	2.64	19.96	2.73

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Appendix F. Statistical Data

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7/13/2000

STATISTICAL ANALYSIS SUMMARY

Testing at Battelle on 299 MA Autoinjector pens from manufacturing lot 8M1511 produced four functionality-related measures for each pen. Specifically,

1. Firing Force (recorded in pounds);
2. Time of Delivery (seconds);
3. Needle Length (millimeters); and,
4. Volume Delivered (milliliters).

The procedures by which these measures were collected are reported elsewhere. The data were extensively reviewed for data entry accuracy (the details of which are also reported elsewhere) and electronically transmitted as a Microsoft Excel 97 file (Data Record.xls). Open Database Connectivity (ODBC) compliant procedures were used to electronically extract the data directly from the Excel file into SAS 8 (i.e., no file conversion or re-entry) for analysis purposes.

Figures 1 through 4 present frequency histograms of firing force, time of delivery, needle length, and volume delivered, respectively, observed for the 299 pens. Superimposed on each histogram are three red vertical lines indicating (from left to right) the lower specification limit, the lot release result reported by Meridian, and the upper specification limit. Also superimposed on Figures 1 through 4 are five green vertical lines indicating (from left to right) the estimated 1st, 5th, 50th, 95th, and 99th quantiles (i.e., measured values below which the specified percentage of tested pens are observed). A broader range of estimated quantiles are reported, for each functionality measure, in Table 1. These quantiles were estimated directly from the available data; no assumptions regarding the data's distribution were required.

Even a cursory review of Figures 1 through 4 reveals none of the tested pens evidenced values beyond specifications. Since 0 out of 299 pens exceeded a given measure's specifications, an exact 95 percent upper confidence bound on the true probability of exceeding that specification equals 0.01[1]. In other words, with 95 percent confidence we conclude, for each of the four measures, the true frequency of pens beyond the specifications is less than 1 in 100. A 99 percent upper confidence bound on the true exceedance probability is 0.015. These bounds are estimated using binomial distribution theory[2] that considers the results from a pass/fail perspective.

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[1] As no exceedances were observed, a 100 percent lower confidence bound of 0.0 is estimated on the true probability of exceeding specifications.

[2] It can be shown (Hollander, M., Wolfe, D.A. "Nonparametric Statistical Methods," John Wiley & Sons, Inc. 1973, p. 24) that an exact 95 percent upper confidence bound on the exceedance probability is,

$$1-\frac{n-s}{(n-s)+(s+1)\cdot F_{0.05}[2\cdot(s+1),2\cdot(n-s)]},$$

where n equals the number of pens and s equals the number exceeding specifications.

Table 1. Estimated (Empirically) Quantiles for Specified Percentages of 299 Tested Pens

Measurement	Units	Estimated Quantiles								
		1%	5%	10%	25%	50%	75%	90%	95%	99%
Firing Force	pounds	4.1	4.7	5.0	5.4	5.8	6.1	6.3	6.5	6.8
Time of Delivery	seconds	2.31	2.40	2.44	2.50	2.57	2.65	2.79	3.22	4.37
Needle Length	millimeters	19.14	19.44	19.56	19.80	19.96	20.12	20.24	20.32	20.38
Volume Delivered	milliliters	2.615	2.679	2.694	2.714	2.728	2.753	2.824	2.852	2.877

The exact upper confidence bound reported above makes no assumptions regarding the distribution of each collected measure. In effect, the bounds mathematically acknowledge only that none of 299 tested pens exceeded specifications, not how close/far the tested pens came to doing so. This can only be accomplished by assuming some character to each measure's distribution (i.e., defining the character to the tails extending beyond the observed data and beyond the specifications). To accomplish this, five candidate distributions—Normal (Gaussian), Lognormal, Weibull, Beta, and Gamma—were fitted to the four functionality measures. The Weibull and Lognormal distributions considered included a third, shift parameter (i.e., permitting the fitted curve representing the distribution to initiate at measured values other than zero) thereby broadening the distribution's ability to fit the observed data.

For needle length and firing force, only the Weibull distribution was not rejected (by goodness of fit statistics[3]) as adequately fitting the data observed for the 299 pens. None of the candidate distributions adequately (according to goodness of fit statistics) fitted the volume delivered and time of delivery data. As all five distributions produced comparable fits, however, for the sake of consistency the Weibull distribution was again selected. Figures 5 through 8 superimpose the fitted Weibull distribution on the histograms for firing force, needle length, time of delivery, and volume delivered, respectively. The legend for each figure notes the Weibull distribution's estimated parameters. The superimposed fit curves in Figures 5 through 8 evidence that assuming a Weibull distribution is more viable for firing force and needle length than for time of delivery and volume delivered; a conclusion consistent with the aforementioned goodness of fit statistics. Nonetheless, for each measure Table 2 summarizes the estimated probability of exceedance along with an estimated 95 percent confidence interval on the true probability of exceedance. A bootstrap resampling procedure was utilized to estimate the confidence interval.[4] Also reported in Table 2 are the 5th, 50th, and 95th quantiles for each functionality measure as estimated from the fitted Weibull distribution. The viability of assuming the fitted Weibull distribution may be assessed by comparing these quantiles to those in Table 1.

[3] Goodness-of-fit tests utilized were the Chi-Square and Empirical Distribution Function tests. Among the latter were the Kolmogorov-Smirnov, Anderson-Darling and Cramer-von Mises tests.

[4] An exact solution would require extensive calculations and asymptotic procedures were deemed inappropriate given the assumed distributions.

If a Weibull distribution is suitable, Table 2 indicates the true frequency of pens exceeding either specification is estimated at less then or equal to 3 in a million for firing force, 2 in a billion for time of delivery, 1 in 10,000 for needle length, and 8 in 10,000 for volume delivered. Conversely, the 95 percent lower confidence bound on the true percentile of manufactured pens exceeding the specification limits is at least 2 in a 10,000,000 for firing force, virtually zero for the time of delivery, 2 in 100,000 for needle length, and 2 in 10,000,000 for volume delivered. Taken as a whole, then, the results in Table 2 indicate MA Autoinjector pens exceeding the manufacturing specifications will be produced only very infrequently.

Table 2. Predicted Quantiles and Estimated Probability (with 95 Percent Confidence Interval) of Manufacturing a Pen Exceeding Specifications

Measure	Units	Predicted Quantiles			Predicted Percentile of Manufactured Pens With Measured Value			95% Confidence Interval on Percentile of Manufactured Pens Exceeding Specifications	
		5%	50%	95%	Below Lower Specification	Above Upper Specification	Exceeding Either Specification	Lower Bound	Upper Bound
Firing Force	pounds	4.7	5.8	6.5	9.74E-05	5.90E-18	9.74E-05	2.10E-05	2.98E-04
Time of Delivery	seconds	2.32	2.59	3.16	0.00E+00	1.01E-13	1.01E-13	3.73E-27	1.92E-07
Needle Length	millimeters	19.42	19.97	20.29	4.70E-03	0.00E+00	4.70E-03	1.95E-03	9.78E-03
Volume Delivered	milliliters	2.654	2.738	2.827	0.00E+00	2.19E-04	2.19E-04	1.62E-05	7.72E-02

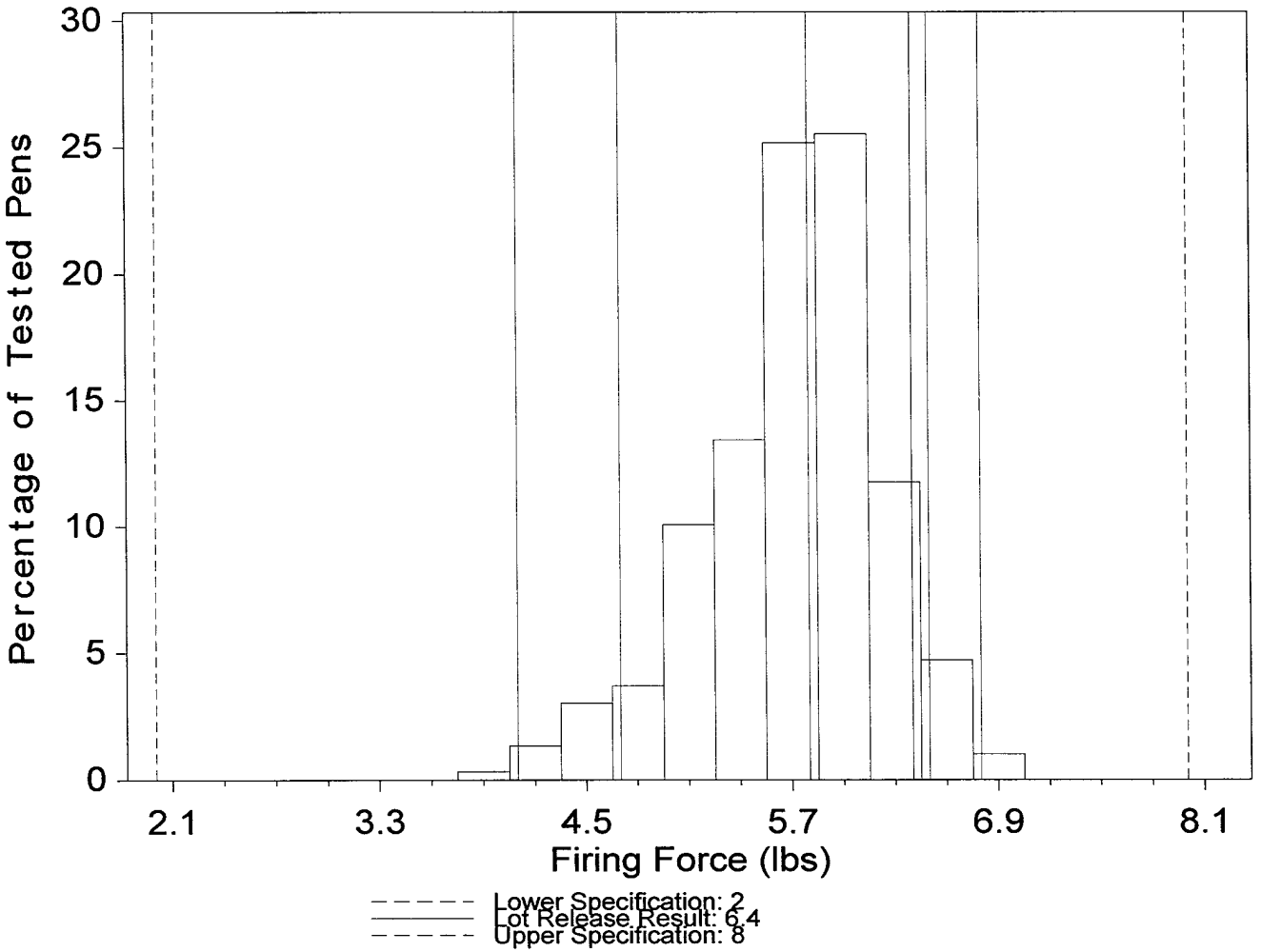

Figure 1. Histogram of Firing Force with Superimposed Specification Limits and Percentiles

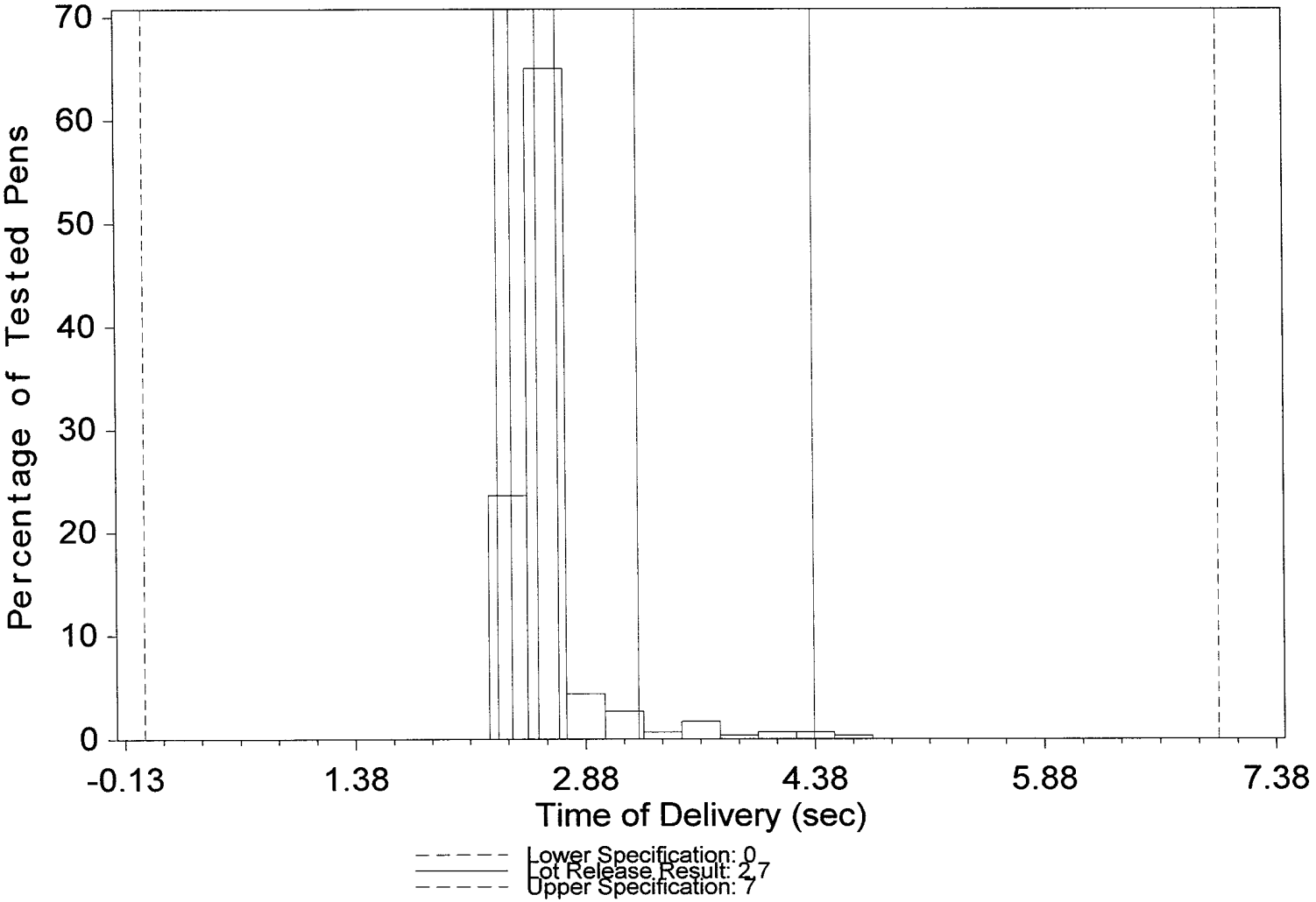

Figure 2. Histogram of Time of Delivery with Superimposed Specification Limits and Percentiles

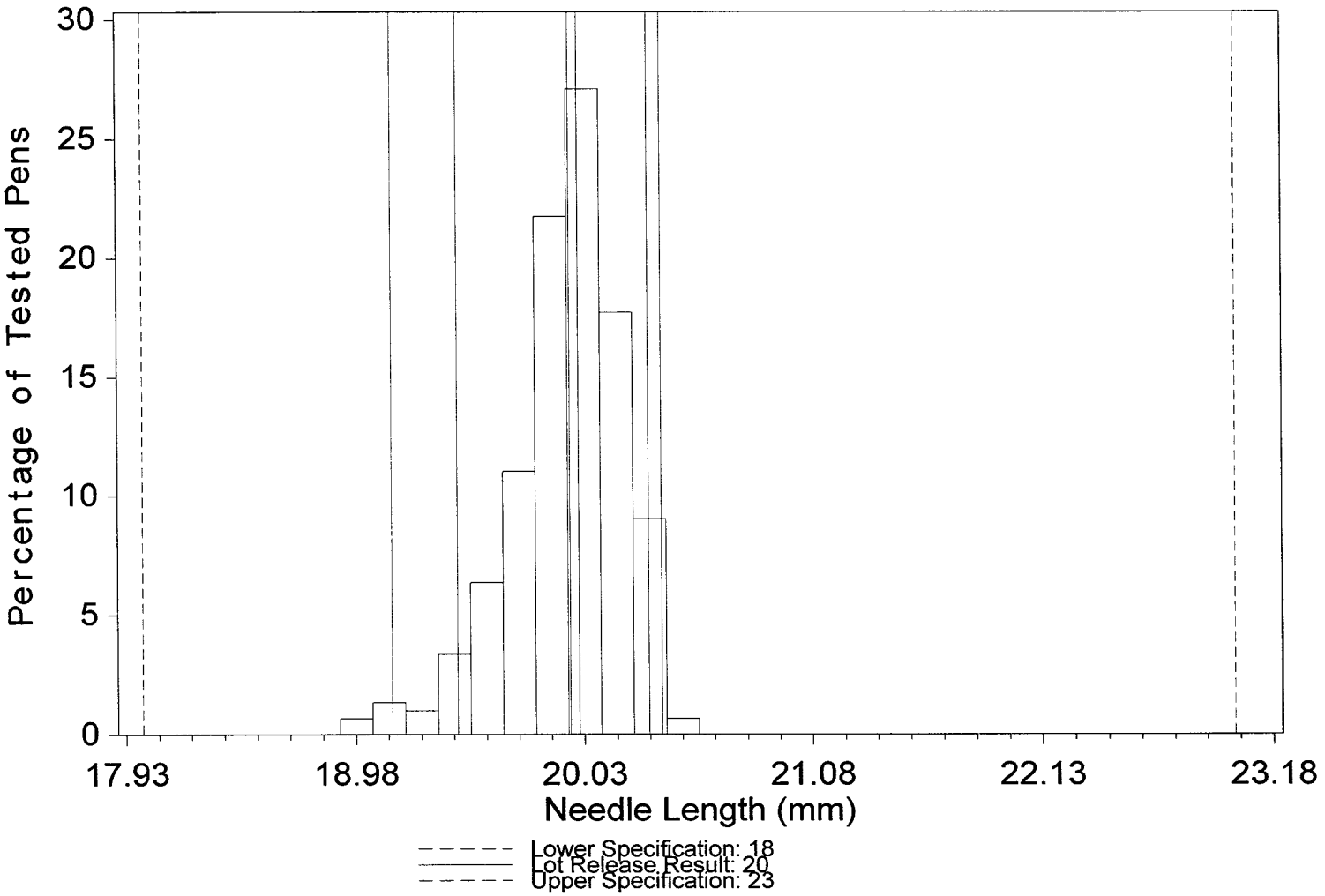

Figure 3. Histogram of Needle Length with Superimposed Specification Limits and Percentiles

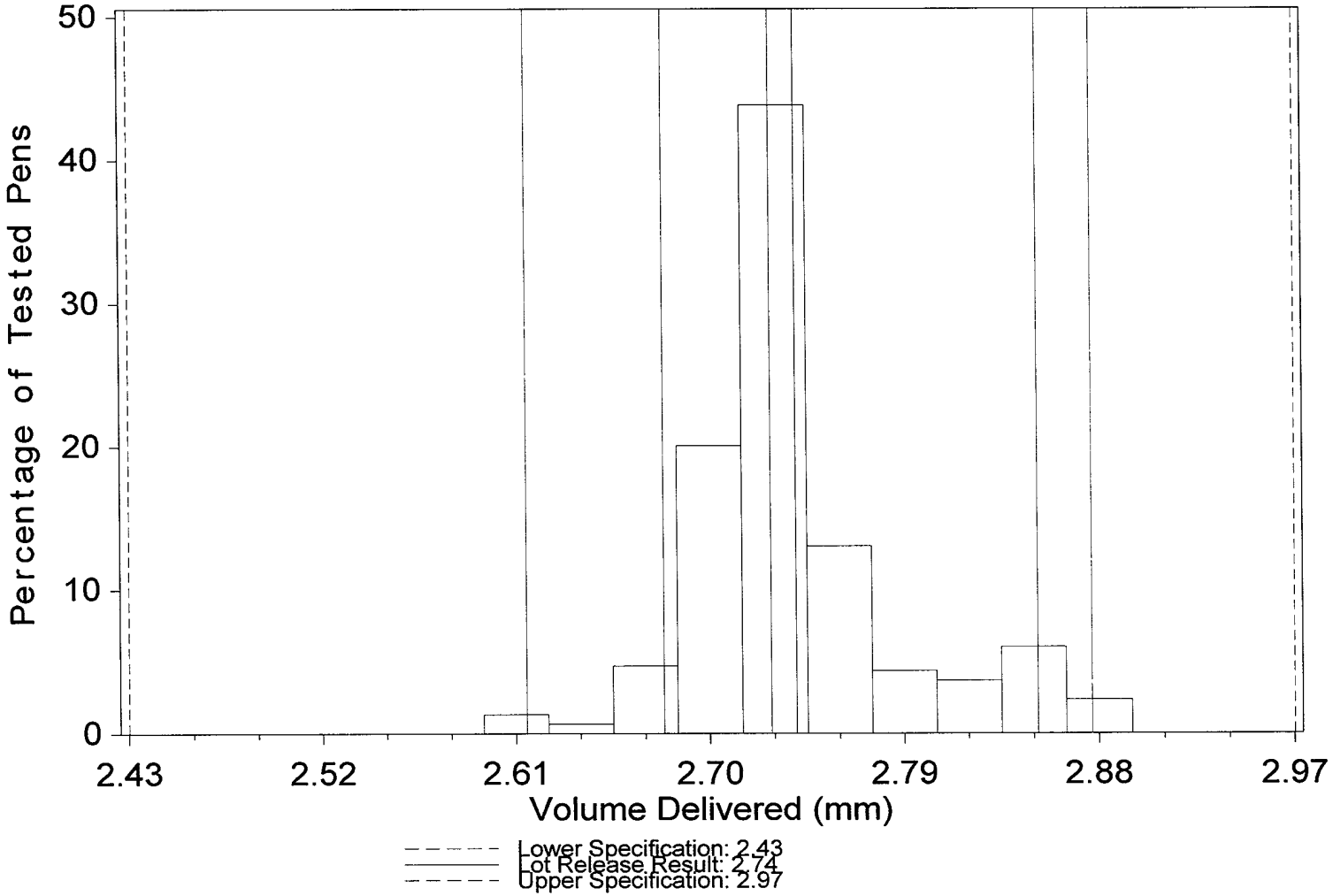

Figure 4. Histogram of Volume Delivered with Superimposed Specification Limits and Percentiles

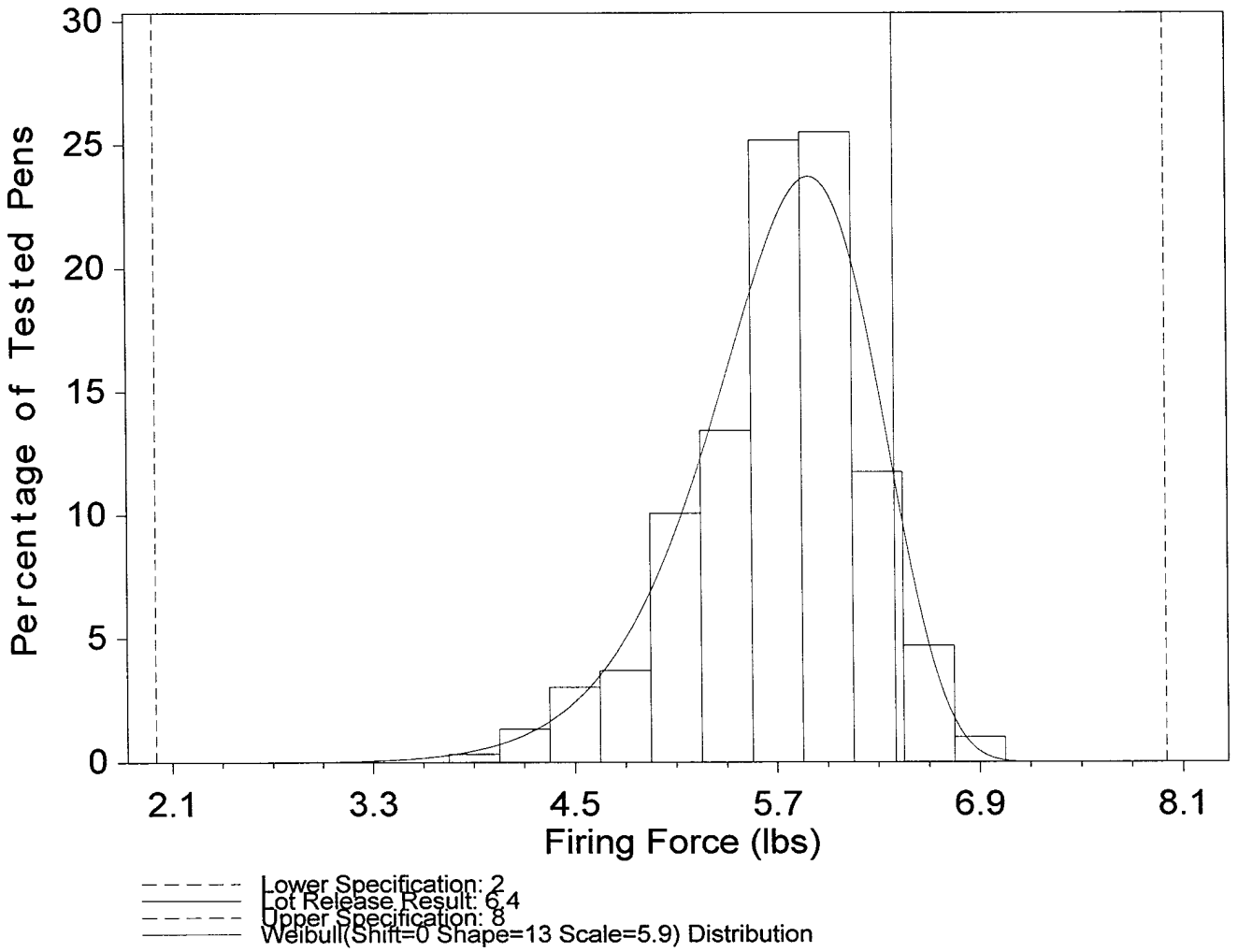

Figure 5. Histogram of Firing Force with Superimposed Specification Limits and Weibull fit

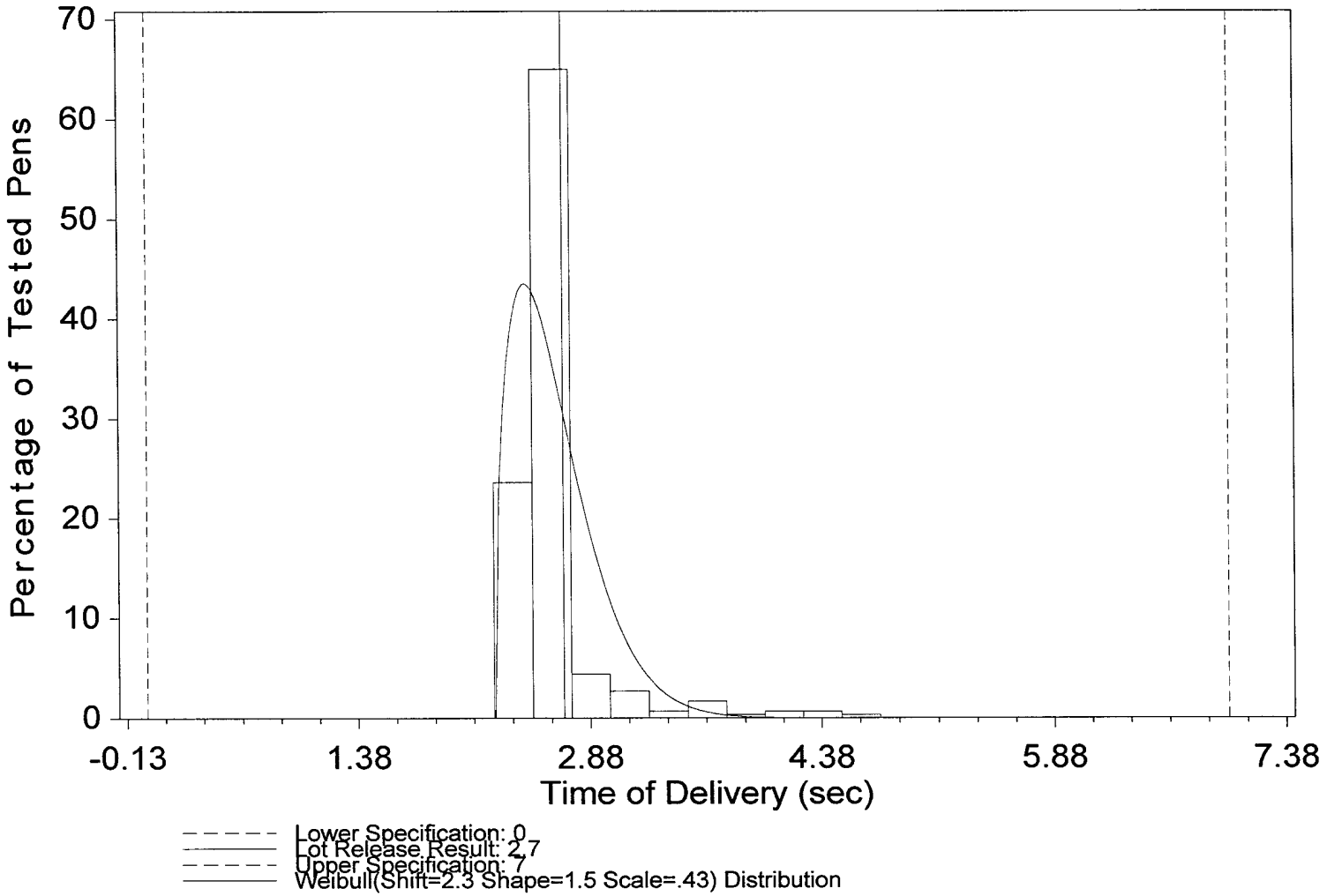

Figure 6. Histogram of Time of Delivery with superimposed Specification Limits and Weibull fit

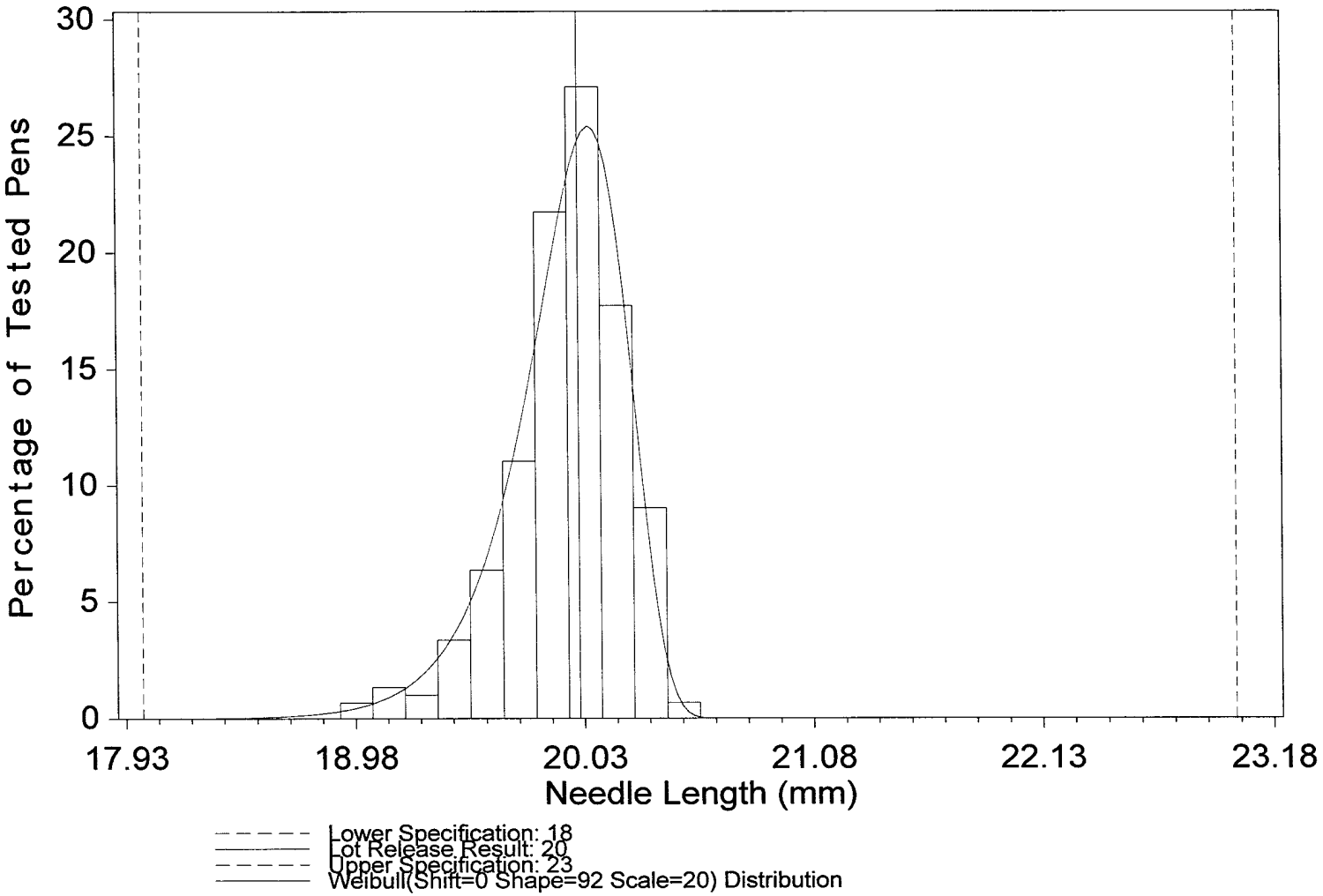

Figure 7. Histogram of Needle Length with Superimposed Specification Limits and Weibull fit

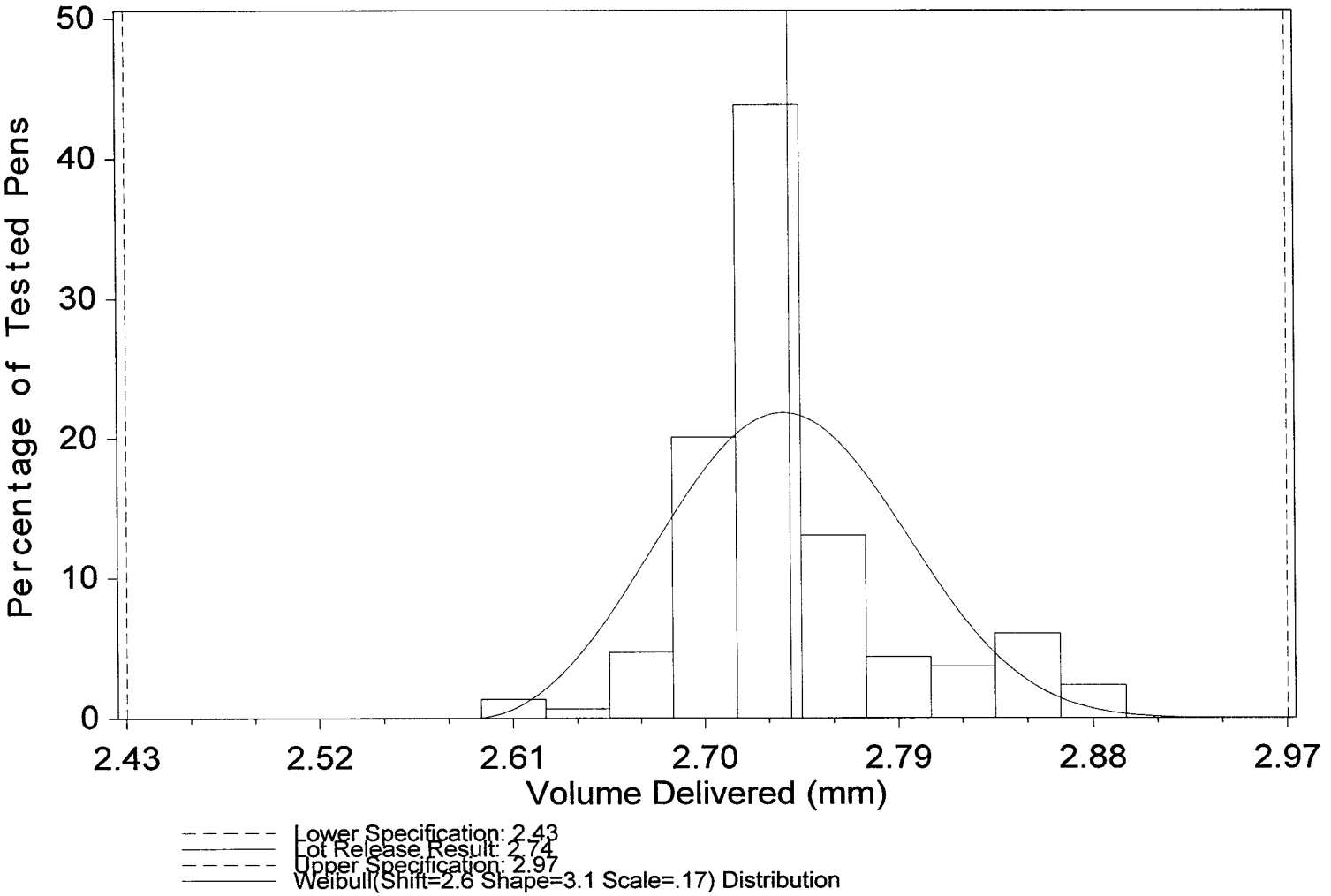

Figure 8. Histogram of Volume Delivered with Superimposed Specification Limits and Weibull fit

Appendix G. Development and Setup

Appendix G

Receipt of Setup and Pretest Units

Battelle received a total of 211 autoinjectors filled with a saline solution for pretesting and setup purposes from Meridian Medical Technologies. One device had already fired, leaving 210 for the pretest. Fifty of these devices were used to perform the preliminary dry-run test sequence under study G472506A, prior to performing the final test study. Another 58 were used for setup purposes. At the end of the study, 102 MA devices were returned to Meridian Medical Technologies.

Preliminary Test of 50 New Autoinjectors

Fifty of the MAs provided to Battelle for setup purposes were used for a dry-run test of the equipment and procedures. The setup MAs were put through the full testing sequence. The results from this dry-run test on the 50 units were compared to data obtained from the manufacturer from testing done at the time of lot release. Table 1 shows a comparison of the specification, lot release data as provided by Meridian Medical Technologies and Battelle's test data. Values shown are the mean for the tested sample.

Table 1: Comparison of the Specification, Lot Release Data and Battelle's Test Data

Attribute	Specification	Lot Release Number M1511	Battelle 50 Unit Test
NL—Needle Length (mm)	18-23	20	20.12
TD—Time of Delivery (secs)	Not more than 7	2.7	2.46
FF—Firing Force (lbs)	2.0 – 8.0	6.4	5.55
DV—Dispensed Volume Saline (ml)	2.43 – 2.97	2.74	2.70