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Title: Zip Pen Flow Evaluation Test Report

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ENG-RPT-403 Zip Flow Testing

Change Request

Name/Signature	Title	Date	Meaning/Reason
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Collaboration

Name/Signature	Title	Date	Meaning/Reason
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Paul Borgmeier (PBORGMEIER)		12 Feb 2018, 03:56:59 PM	Complete
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Mallory Schroeder (MSCHROEDER)	Engineer	20 Feb 2018, 10:55:13 AM	Complete

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Paul Borgmeier (PBORGMEIER)		20 Feb 2018, 11:07:52 AM	Approved

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Final Release

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Authored By: Mark Glassett
Revised By: Mallory Schroeder (M.S.)

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1. ABSTRACT

Zip Pen Catalog # 2525-15 samples were tested per the requirements of ENG-PRT-280 to evaluate flow characteristics with different smoke evacuator devices. The performance of the Zip Pen was compared with the predicate device 2110-10 UltraVac (Megadyne branded version of the IC Medical Penevac). The Zip Pen met the requirement of the protocol of having equal or greater flow than the predicate. The reaction of the Zip Pen under occlusion conditions was also observed. There was no damage to the product and the tubing does not collapse radially under occlusion.

2. OBJECTIVE

The objective of this test report is to document equivalence of flow rate of the Zip Pen with the predicate UltraVac. The testing also determined an upper flow rate value where the Zip Pen can be safely used. The report documents the reaction of the device under occlusion to insure it is not damaged and remains functional after an occlusion event.

3. RESULTS

3.1. Zip Pen Flow Test

The Zip Pen was tested for flow in comparison with the UltraVac using the following smoke evacuator devices set at maximum flow.

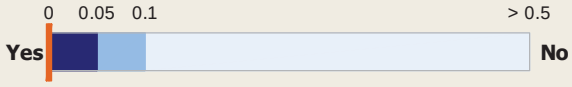
Megadyne Mega Vac Plus
Buffalo Filter Viro Vac

Conmed AER Defense
Lina Safe Air SFR-0200

3.1.1. **Mega Vac Plus**: The 't' test analysis below shows that the Zip Pen has higher flow than the Ultra Vac when attached to the Mega Vac Plus and therefore meets the requirements of the protocol.

2-Sample t Test for the Mean of Zip Pen and Ultra Vac
Summary Report

Mean Test
Is Zip Pen greater than Ultra Vac?

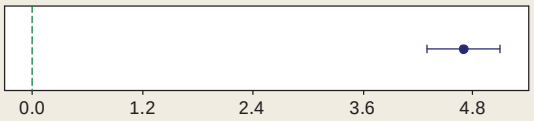


P = 0.000
The mean of Zip Pen is significantly greater than the mean of Ultra Vac (p < 0.05).

Statistics	Zip Pen	Ultra Vac
Sample size	11	11
Mean	71.705	67.005
90% CI	(71.59, 71.82)	(66.614, 67.395)
Standard deviation	0.20656	0.71500

Difference between means* 4.7
90% CI (4.2970, 5.1030)
* The difference is defined as Zip Pen - Ultra Vac.

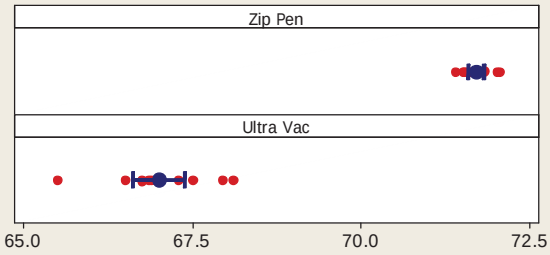
90% CI for the Difference
Does the interval include zero?



Comments

-- Test: You can conclude that the mean of Zip Pen is greater than Ultra Vac at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 90% confident that the true difference is between 4.2970 and 5.1030.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

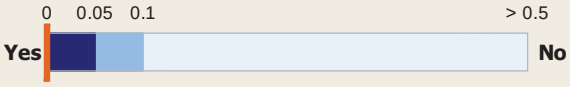
Distribution of Data
Compare the data and means of the samples.



3.1.2 **Buffalo Filter Viro Vac**: The 't' test analysis below shows that the Zip Pen has higher flow than the Ultra Vac when attached to the Buffalo Filter Viro Vac and therefore meets the requirements of the protocol.

2-Sample t Test for the Mean of Zip Pen and Ultra Vac
Summary Report

Mean Test
Is Zip Pen greater than Ultra Vac?

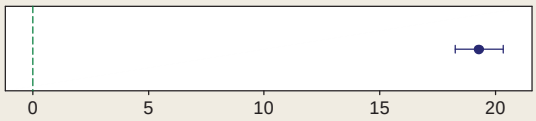


P = 0.000
The mean of Zip Pen is significantly greater than the mean of Ultra Vac (p < 0.05).

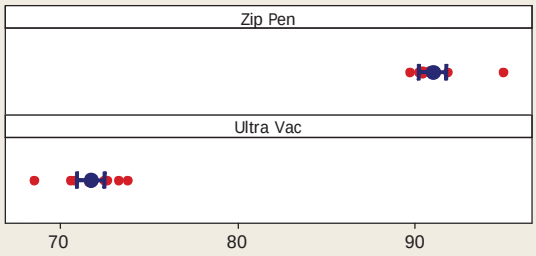
Statistics	Zip Pen	Ultra Vac
Sample size	11	11
Mean	91	71.718
90% CI	(90.21, 91.79)	(70.931, 72.505)
Standard deviation	1.4374	1.4400

Difference between means* 19.282
90% CI (18.221, 20.343)
* The difference is defined as Zip Pen - Ultra Vac.

90% CI for the Difference
Does the interval include zero?



Distribution of Data
Compare the data and means of the samples.



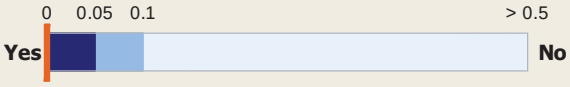
Comments

-- Test: You can conclude that the mean of Zip Pen is greater than Ultra Vac at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 90% confident that the true difference is between 18.221 and 20.343.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

3.1.3 **Conmed AER Defense**: The 't' test analysis below shows that the Zip Pen has higher flow than the Ultra Vac when attached to the Conmed AER Defense and therefore meets the requirements of the protocol.

2-Sample t Test for the Mean of Zip Pen and Ultra Vac
Summary Report

Mean Test
Is Zip Pen greater than Ultra Vac?

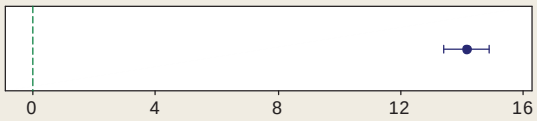


P = 0.000
The mean of Zip Pen is significantly greater than the mean of Ultra Vac (p < 0.05).

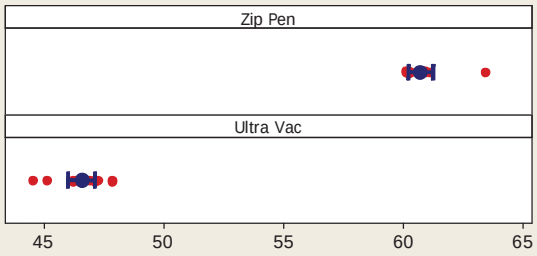
Statistics	Zip Pen	Ultra Vac
Sample size	11	11
Mean	60.727	46.564
90% CI	(60.20, 61.25)	(45.993, 47.134)
Standard deviation	0.95717	1.0433

Difference between means* 14.164
90% CI (13.425, 14.902)
* The difference is defined as Zip Pen - Ultra Vac.

90% CI for the Difference
Does the interval include zero?



Distribution of Data
Compare the data and means of the samples.



Comments

-- Test: You can conclude that the mean of Zip Pen is greater than Ultra Vac at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 90% confident that the true difference is between 13.425 and 14.902.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

3.1.4 **LINA Safe Air SFR-0200**: The 't' test analysis below shows that the Zip Pen has higher flow than the Ultra Vac when attached to the LINA Safe Air SFR-0200 and therefore meets the requirements of the protocol.

2-Sample t Test for the Mean of Zip Pen and Ultra Vac
Summary Report

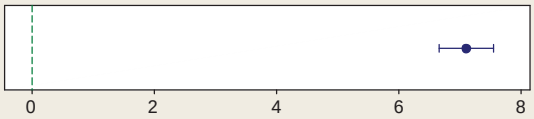
Mean Test
Is Zip Pen greater than Ultra Vac?

P = 0.000
The mean of Zip Pen is significantly greater than the mean of Ultra Vac (p < 0.05).

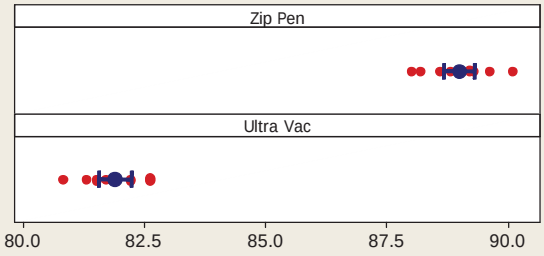
Statistics	Zip Pen	Ultra Vac
Sample size	11	11
Mean	89	81.891
90% CI	(88.67, 89.33)	(81.564, 82.218)
Standard deviation	0.59833	0.59909

Difference between means* 7.1091
90% CI (6.6677, 7.5505)
* The difference is defined as Zip Pen - Ultra Vac.

90% CI for the Difference
Does the interval include zero?



Distribution of Data
Compare the data and means of the samples.



Comments

-- Test: You can conclude that the mean of Zip Pen is greater than Ultra Vac at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 90% confident that the true difference is between 6.6677 and 7.5505.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

3.1.5 Data Summary

Smoke Evacuator	2525-15 Zip Pen Flow Avg.	Ultra Vac Flow Avg.
Mega Vac Plus	71.7 lpm	67.0 lpm
Buffalo Filter Viro Vac	91.0 lpm	71.7 lpm
Conmed AER Defense	60.7 lpm	46.6 lpm
Lina Safe Air	89.0 lpm	81.9 lpm

3.2. Maximum Flow Rate Evaluation

Prior to Zip Pen testing the maximum flow of each smoke evacuator with filter was checked. This data is shown in comparison to the Zip Pen average flow rate for that smoke evacuator. The measured values are as follows:

Smoke Evacuator	Max Open Flow	2525-15 Zip Pen Flow Avg.
Mega Vac Plus	78.5 lpm	71.7 lpm
Buffalo Filter Viro Vac	358.2 lpm	91.0 lpm
Conmed AER Defense	258.7 lpm	60.7 lpm
Lina Safe Air	100.6 lpm	89.0 lpm

The above values illustrate a large range of flow rates for the different smoke evacuator devices. They all use different technologies for the vacuum source but when the Zip Pen (or competitive smoke evacuation pencil) is attached the restriction of the device lowers the flow down to a much lower value. Note that the higher flow rate of the smoke evacuator does not correlate linearly with the flow rate of the Zip Pen. This no linearity is due to the ability of the smoke evacuator to produce vacuum pressure. The Mega Vac Plus and the Lina Safe Air can produce more vacuum pressure and therefore the drop in flow from the Max Open Flow to the flow with the Zip Pen is small. Conversely, the Buffalo Filter Viro Vac and the Conmed AER Defense only produce a small amount of vacuum and therefore the drop in flow from the Max Open Flow to the flow with the Zip Pen is large.

3.3. Tubing Occlusion Evaluation

For each smoke evacuator, the effect on the Zip Pen during occlusion was observed. The following comments were recorded.

Mega Vac Plus: Tubing collapsed and accordioned , no kinking or blockages
Buffalo filter Viro Vac: Tubing collapsed slightly and accordioned , no kinks or blocks
Conmed AER Defense: Movement in tubing barely noticeable when occluded
Lina Safe Air SFR-0200: Tubing accordioned quite strongly, but did not kink or impede flow in any way.

Reviewing the comments with the technician, the tubing did not collapse radially but rather along the axis in an accordion motion. The accordion condition relaxes back to the normal tubing length when the occlusion is discontinued. This is the

expected result for convoluted tubing. There was no damage to the Zip Pen as a result of occlusion, therefore the Zip Pen passes the protocol.

4. DISCUSSION

Zip Pen catalog number 2525-15 with 15 ft tubing Lot S140045 were used for this testing. The Zip Pen with 15 foot tubing is the worst case representation for the Zip Pen in terms of flow because this is the longest available tubing. These also represent the 2525-10 product that has 10 foot tubing. The comparison device was Ultra Vac 2110-10 Lot 5408 with ten foot tubing.

Prior to testing, the Zip Pen samples were gamma sterilized to a minimum of 50 kGy. The samples were also artificially aged at 55°C for 111 days to simulate three years shelf life. The samples were exposed to thermal cycling from -40°C to 70 °C to simulate worst case shipping environment. The samples were preconditioned for ship testing and then subjected to the ship test. These conditions were performed to simulate worst case sterilization and handling prior to reaching the customer. Documentation of this treatment for this lot of samples is shown in ENG-RPT-377.

4.1. Zip Pen Flow Test

The Zip Pen was tested per the protocol for flow in comparison with the UltraVac using common smoke evacuators found in the market. The flow data with Zip Pen shows that it has higher flow characteristics of the two devices. This is expected because the Zip Pen has a slightly larger minimum cross sectional area than the Ultra VAC.

4.2. Maximum Flow Rate Evaluation.

This evaluation was done to show that with the large variation of flow values from the smoke evacuator devices, the flow through the Zip Pen is still equal to or greater than the Ultra Vac predicate. The flow with the smoke evacuation pencil attached meets the requirement of the protocol.

4.3. Tubing Occlusion Evaluation

The tubing occlusion evaluation demonstrates that the tubing remains patent during and after occlusion. There was no damage to the Zip Pen as a result of occlusion.

5. CONCLUSIONS

This testing demonstrates that the Zip Pen catalog numbers 2525-10 and 2525-15 meet the requirement that the flow is equal to or greater than the Ultra Vac 2110-10 when used with the Megadyne Mega Vac Plus smoke evacuator.

This testing demonstrates that the Zip Pen has equivalent or greater flow rate than the Ultra Vac when used with competitive smoke evacuator devices.

This testing demonstrates that the Zip Pen can be used with smoke evacuator devices that have flow rates as high as 358 lpm.

This testing demonstrates that the Zip Pen is not damaged when fully occluded.

6. RECOMMENDATIONS

This test report will be archived in the Zip Pen Design History Record.

7. REVISION HISTORY DESCRIPTION

The purpose of revision 002 of this document is to address a typo in the Appendix data sheets. The operator mistakenly recorded 2525-10 instead of 2525-15 in the catalog number field. Appendix V provides further evidence that lot number S140045 is catalog number 2525-15.

Appendix I:
ZIP PEN FLOW TEST LOG SHEET
Mega Vac Plus

M.S. 1/8/18 Fix incorrectly recorded catalog number

Appendix I:
Zip Pen Flow Test Data Sheet
Mega Vac Plus

2525-15

Zip Pen Catalog# 2525-10 Lot# S140045

Ultra Vac Catalog# 2110-10 Lot# 5408

Mega Vac Plus S/N I4211

ULPA Filter Lot# 5058

Maximum Flow of the Mega Vac Plus 78.48

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-15	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.	72.05	1.	65.50
2.	71.57	2.	67.95
3.	71.63	3.	66.75
4.	71.82	4.	67.50
5.	71.82	5.	66.95
6.	71.52	6.	66.75
7.	71.69	7.	66.50
8.	72.02	8.	66.90
9.	71.53	9.	68.10
10.	71.70	10.	66.85
11.	71.40	11.	67.30

Comments on Zip Pen Occlusion: Tubing collapsed and accordioned, no kinking or blockages.

Test Performed by: Paul Valpreda Date: 11-5-2014

Appendix II
ZIP PEN FLOW TEST LOG SHEET
Buffalo Filter Viro Vac

Appendix II:
Zip Pen Flow Test Data Sheet
Buffalo Filter Viro Vac

M.S. 1/8/18 Fix incorrectly recorded catalog number

2525-15

Zip Pen Catalog# 2525-10 Lot# S140045

Ultra Vac Catalog# 2110-10 Lot# 5408

Viro Vac S/N V00325

Maximum Flow of the Buffalo Filter Viro Vac 358.20

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-15	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.	90.4	1.	68.5
2.	91.2	2.	71.6
3.	90.4	3.	71.9
4.	91.8	4.	72.6
5.	90.3	5.	73.3
6.	90.8	6.	70.8
7.	90.4	7.	71.6
8.	95.0	8.	72.5
9.	89.7	9.	73.8
10.	90.8	10.	70.6
11.	90.2	11.	71.7

Comments on Zip Pen Occlusion: Tubing collapsed slightly and accordioned. No kinks or blocks.

Test Performed by: Paul Valpreda Date: 11-5-2014

Appendix III
ZIP PEN FLOW TEST LOG SHEET
Conmed AER Defense

M.S. 1/8/18 Fix incorrectly recorded catalog number

Appendix III:
Zip Pen Flow Test Data Sheet
Conmed AER Defense

2525-15

Zip Pen Catalog# 2525-10 Lot# S140045

Ultra Vac Catalog# 2110-10 Lot# 5408

AER Defense S/N 12DCAØØ1

Maximum Flow of the Conmed AER Defense 258.7

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-15	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.	60.9	1.	44.5
2.	60.2	2.	46.3
3.	60.3	3.	47.2
4.	60.2	4.	47.1
5.	60.2	5.	47.8
6.	60.9	6.	46.2
7.	60.6	7.	46.9
8.	63.4	8.	47.1
9.	60.1	9.	47.8
10.	61.1	10.	45.1
11.	60.1	11.	46.2

Comments on Zip Pen Occlusion: Movement in tubing barely noticable when occluded.

Test Performed by: Paul Valpreda Date: 11-5-2014

Appendix IV
ZIP PEN FLOW TEST LOG SHEET
Lina Safe Air SFR-0200

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number XENG-PRT-280
	Zip Pen Flow Evaluation Protocol	Revision: A
		Page 9 of 9

M.S. 1/8/18 Fix incorrectly recorded catalog number

Appendix VI:
Zip Pen Flow Test Data Sheet
Lina Safe Air SFR-0200

2525-15

Zip Pen Catalog# 2525-10 Lot# S1400045

Ultra Vac Catalog# 2110-10 Lot# 5408

Safe Air S/N 13035-3

Maximum Flow of the Lina Safe Air SFR-0200 100.6

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-15 Flow	Sample #	Ultra Vac 2110-10 Flow
1.	89.0	1.	80.8
2.	89.0	2.	81.7
3.	88.2	3.	81.5
4.	89.6	4.	82.2
5.	88.0	5.	82.6
6.	90.1	6.	81.3
7.	89.3	7.	81.8
8.	89.2	8.	82.6
9.	89.2	9.	82.6
10.	88.8	10.	81.5
11.	88.6	11.	82.2

Comments on Zip Pen Occlusion: Tubing accordioned quite strongly, but did not kink or impede flow in any way.

Test Performed by: Paul Valpreda Date: 11-6-2014

Appendix V

2525-15 Lot Number S140045

NEW DEANTRONICS
New Deantronics Group

NEW DEANTRONICS TAIWAN, LTD. WITH QUALITY SYSTEM CERTIFIED BY BAV ISO 13485:2003

Certificate of Compliance

Taiwan
大德企業股份有限公司
New Deantronics Taiwan, Ltd.
新北市土城區中央路4段51號
12F., No.51, Sec.4,
Chong Yang Rd., Tu Chong Dist.,
New Taipei City 23575,
Taiwan R.O.C.
Tel: +886 2 2268-1726
Fax: +886 2 2268-3600

USA
New Deantronics Ltd.
1990 North California Blvd.
Suite 1040
Walnut Creek, CA. 94596
Tel: +1 (925) 280-6368
Fax: +1 (925) 280-1788

Customer Name: MEGADYNE MEDICAL PRODUCTS, INC.
Invoice Number : MD-441/14
P. O. Number: 23954
Customer P/N: X2525-15
Drawing Number: X2525-15 Rev.02
New Deantronics P/N: PB752SM1
Lot Number: S140045
Expiration Date: N/A
Quantity: 40 Pieces
Carton Number: #1 ~ #2 (2 Cartons)

Signed: D. Y Chen **Date:** 03-05-2014
Printed Name: Da-Yu Chen
Title: Q.A. Director

Note: Aging sample for sealing test

Materials		ND Mat'l Lot#	Megadyne Lot#
Cable	C302600 Conductor : 7/0.16*3BC(26 AWG) Bare copper Insulation: PPE, one red, one blue & one white Outer jacket: PVC, Gray	131014Z	
Plug material	F505100, TOP, ABS PA707 F505200, Bottom, ABS PA707	130917 130917	
Terminal	T101702 Brass	131030	
PCB Overmold	R900801, TPR	130801	
Swivel, male	F916600, HDPE	S130301	
Swivel, Female	F917000, HDPE	S130301	
Connector Proximal	F916800, LDPE	131231	
Collet Terminal	T202502, Phosphor Bronze contact plated nickel	130904	
Button	F302500, NYLON 66	131217	
Tape	A100401, PTFE	131002	
PCB	H201602, PCB FR-4	140211	
Dome	M100600, 6mm ROUND W/DIMPLE & FEET	130820	
Pen Body	F105400, ABS+TPR	131217	

QR-002-2

1/2

NEW DEANTRONICS
New Deantronics Group

NEW DEANTRONICS TAIWAN, LTD. WITH
QUALITY SYSTEM
CERTIFIED BY DNV
= ISO 13485:2003 =

Taiwan
New Deantronics Taiwan, Ltd.
12F., No.51, Sec 4,
Chong Yang Rd., Tu Cheng Dist.,
New Taipei City 23675,
Taiwan R.O.C.
Tel: +886 2 2268-1726
Fax: +886 2 2268-3800

USA
New Deantronics Ltd.
1990 North California Blvd.
Suite 1040
Walnut Creek, CA 94596
Tel: +1 (925) 280-8388
Fax: +1 (925) 280-1788

Nozzle	F916300, PC	131217	
Collet Holder	F918100, PC	131217	
Carriage	F916500, ABS	131217	
Snap Swivel, Male	F916400, HDPE	S130302	
Snap Swivel, Female	F918300, HDPE	S130302	
Tubing, Connector	F916700, HDPE	S130318	
Tubing, Convoluted	P305600, EVA 8.5"	130828	
Tubing, Convoluted	P305700, EVA 56"	130828	
Holster	F916900, HDPE	131220	
Blade	G102700, Coated Megadyne P/N: 0012BN5 (Provided by Megadyne)	140121 (40pcs)	134585
Paper Band	A900300	140116	
Tyvek	A000400	140116	
Nylon Film	A000500	131217	
Glue	S400900, Loctite 4061	130409	
Ink	S102000, Green, PMS356C	121127	
IFU PN and REV	P/N3000185-01 Rev.A	130910	

QR-002-2

03/05/2014/周3 03:52 PM FAX No. P. 005

中國生化科技股份有限公司
CHINA BIOTECH CORPORATION
TEL:886-4-23597515 FAX:886-4-23597080
台中市工業區33路10號
10, 33rd Road, Taichung Industrial Park,
Taichung,Taiwan R.O.C 407

DATE：2014/3/5

照射證明書
CERTIFICATE OF IRRADIATION

REVISED

行政院原能會核准設立照射廠執照証號 IRRADIATION PLANT NO：物字第 1100223 號

客戶名稱 CUSTOMER NAME：大瓏企業(股)公司
NEW DEANTRONICS TAIWAN LTD.

照射日期 IRRADIATION RUN DATE：2014/02/27

照射批號 IRRADIATION RUN NUMBER：NEW14134-J1

客戶產品已照射 MATERIALS PROCESSED：

箱數 CASE		內容 DESCRIPTION	客戶產品批號 LOT NO
1	(40PCS)	X2525-15 PB752SM1	S140045

總數 TOTAL 1 箱數 CASE

中國生化科技股份有限公司證明上述產品經本公司劑量偵測系統判讀，吸收劑量如下：
China Biotech Corporation certifies that the material listed above (has described by its manufacturer) received the following doses within the precision limits of the dosimetry system employed

最低劑量 MINIMUM DOSAGE 51.7 kGy；最高劑量 MAXIMUM DOSAGE 54.2 kGy

使用放射性同位素 ISOTOPE UTILIZED ：鈷 60 COBALT-60

客戶劑量要求 DOSE REQUIREMENT ：最低劑量MIN 50.0 kGy；最高劑量MAX 60.0 kGy

確認者：
CERTIFIED BY
品保部主管
QUALITY ASSURANCE

確保人類健康・珍惜自然環境