



PROTOCOL

PTL-903012

Rev: 002

Data Sheets

DOCUMENT OWNER: R&amp;D

## Executor Traceability Sheet

Note: This page may be copied as necessary.

Sheet # 1 of 1 2/22/21Group DROP

Printed Name	Department and Title	Signature	Initials	Date
Lindsay Densmore	DVT Medical Device Engineer 1	<i>Lindsay Densmore</i>	LD	2/11/21
RONALD TRISTAN GALANG	DVT ENGINEERING TECHNICIAN 2	<i>Ronald Tristan Galang</i>	RTG	02/11/2021
N/A <i>2/22/21</i>				

(Print, Sign, & Date) Reviewer: Abigail Corn Abgler 2/22/21

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## TP-90742 Data Sheet 1 – Drop Orientations

Note: This page may be copied as necessary.

Sheet # 1 of 1Group DROP

Run # <u>1</u>			
A	B		
Specimen #	Drop Orientation		
1	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
2	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
3	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
4	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
5	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
6	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
7	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
8	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
9	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
10	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
11	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
12	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
13	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
14	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
15	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP

Run # <u>1</u>			
A	B		
Specimen #	Drop Orientation		
16	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
17	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
18	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
19	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
20	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
21	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
22	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
23	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
24	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
25	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
26	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
27	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
28	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
29	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP
	TRIGGER DOWN	CAP AT 45 DEGREES	CAP UP

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TP-90755, TP-90756 Results

Note: This page may be copied as necessary.

Sheet # 1 of 3Group DROP

Run # <u>1</u>				
A	B		C	
Specimen #	TP-90755		TP-90756	
	Inner Housing Retention		Wearable Retention	
1	PASS	FAIL	PASS	FAIL
2	PASS	FAIL	PASS	FAIL
3	PASS	FAIL	PASS	FAIL
4	PASS	FAIL	PASS	FAIL
5	PASS	FAIL	PASS	FAIL
6	PASS	FAIL	PASS	FAIL
7	PASS	FAIL	PASS	FAIL
8	PASS	FAIL	PASS	FAIL
9	PASS	FAIL	PASS	FAIL
10	PASS	FAIL	PASS	FAIL
11	PASS	FAIL	PASS	FAIL
12	PASS	FAIL	PASS	FAIL
13	PASS	FAIL	PASS	FAIL
14	PASS	FAIL	PASS	FAIL

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TP-90755, TP-90756 Results

Note: This page may be copied as necessary.

Sheet # 2 of 3Group DROP

Run # <u>1</u>				
A	B		C	
Specimen #	TP-90755		TP-90756	
	Inner Housing Retention		Wearable Retention	
<u>15</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>16</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>17</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>18</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>19</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>20</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>21</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>22</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>23</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>24</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>25</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>26</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>27</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
<u>28</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL

(Initial & Date) Executor: 20 2/11/21 Executor: N/A 20 2/11/21(Print, Sign, & Date) Reviewer: Abigail Corn Abigail Corn 2/18/21

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TP-90755, TP-90756 Results

Note: This page may be copied as necessary.

Sheet # 3 of 3Group DROP

Run # <u>1</u>			
A	B		C
Specimen #	TP-90755		TP-90756
	Inner Housing Retention		Wearable Retention
<u>29</u>	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL
	PASS	FAIL	PASS FAIL

(Initial & Date) Executor: 228 2/11/21Executor: N/A 2/16/21(Print, Sign, & Date) Reviewer: Abigail Corn Abigail 2/18/21

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## TP-90743 Data Sheet 1 – Deployment Tracking

Note: This page may be copied as necessary.

Sheet # 1 of 1Group DROP

Specimen #	Deployment Side	
1	STOMACH	ARM
2	STOMACH	ARM
3	STOMACH	ARM
4	STOMACH	ARM
5	STOMACH	ARM
6	STOMACH	ARM
7	STOMACH	ARM
8	STOMACH	ARM
9	STOMACH	ARM
10	STOMACH	ARM
11	STOMACH	ARM
12	STOMACH	ARM
13	STOMACH	ARM
14	STOMACH	ARM
15	STOMACH	ARM
16	STOMACH	ARM
17	STOMACH	ARM

Specimen #	Deployment Side	
18	STOMACH	ARM
19	STOMACH	ARM
20	STOMACH	ARM
21	STOMACH	ARM
22	STOMACH	ARM
23	STOMACH	ARM
24	STOMACH	ARM
25	STOMACH	ARM
26	STOMACH	ARM
27	STOMACH	ARM
28	STOMACH	ARM
29	STOMACH	ARM
	STOMACH	ARM
	STOMACH	ARM
	STOMACH	ARM
	STOMACH	ARM
	STOMACH	ARM

Note: The Deployment Gel used was Substrate Common Name "Anakin" with a Use-By Date of 03/04/2021. ~~2/11/21~~

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TP-90757, TP-90774 Results

Note: This page may be copied as necessary.

Sheet # 1 of 3Group DROP

Run # <u>1</u>				
A	B		C	
Specimen #	TP-90757		TP-90774	
	Needle Retraction		Sensor Insertion	
1	PASS	FAIL	PASS	FAIL
2	PASS	FAIL	PASS	FAIL
3	PASS	FAIL	PASS	FAIL
4	PASS	FAIL	PASS	FAIL
5	PASS	FAIL	PASS	FAIL
6	PASS	FAIL	PASS	FAIL
7	PASS	FAIL	PASS	FAIL
8	PASS	FAIL	PASS	FAIL
9	PASS	FAIL	PASS	FAIL
10	PASS	FAIL	PASS	FAIL
11	PASS	FAIL	PASS	FAIL
12	PASS	FAIL	PASS	FAIL
13	PASS	FAIL	PASS	FAIL
14	PASS	FAIL	PASS	FAIL

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TP-90757, TP-90774 Results

Note: This page may be copied as necessary.

Sheet # 2 of 3Group DROP

Run # <u>1</u>			
A	B		C
Specimen #	TP-90757		TP-90774
	Needle Retraction		Sensor Insertion
15	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
16	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
17	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
18	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
19	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
20	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
21	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
22	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
23	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
24	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
25	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
26	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
27	<u>PASS</u>	FAIL	<u>PASS</u> FAIL
28	<u>PASS</u>	FAIL	<u>PASS</u> FAIL

(Initial & Date) Executor: 2/11/21 Executor: N/A 2/11/21  
 (Print, Sign, & Date) Reviewer: Abigail corn Abigl Cr 2/18/21

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TP-90757, TP-90774 Results

Note: This page may be copied as necessary.

Sheet # 3 of 3Group DROP

Run # <u>1</u>				
A	B		C	
Specimen #	TP-90757		TP-90774	
	Needle Retraction		Sensor Insertion	
<u>29</u>	<u>PASS</u>	FAIL	<u>PASS</u>	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL
	PASS	FAIL	PASS	FAIL

(Initial & Date) Executor: 2/11/21 Executor: N/A 2/11/21(Print, Sign, & Date) Reviewer: Abigail Corn Abigail 2/18/21



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TP-90758 Data Sheet 1 – Gauge Block Measurements

Sheet # 1 of 1

Note: This page may be copied as necessary.

Group DROP

Run # <u>1</u>	
Position	Gauge Block Width (mm)
A	3.00
B	3.00
C	3.00

(Initial & Date) Executor: RTG 02/11/2021 Executor: N/A ~~2/16/21~~  
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TP-90758 Data Sheet 2 – Sensor Depth Measurements

Sheet # 1 of 1

Note: This page may be copied as necessary.

Group DROP

Run # <u>1</u>		
Specimen #	Dino-Lite Measurement (mm)	Sensor Depth Measurement (mm)
1	2.354	5.735
2	2.336	5.717
3	2.315	5.696
4	2.002	5.383
5	2.240	5.621
6	2.174	5.555
7	2.256	5.637
8	2.147	5.528
9	2.183	5.564
10	2.148	5.529
11	2.028	5.409
12	2.198	5.579
13	2.121	5.502
14	2.240	5.621
15	2.239	5.620

Run # <u>1</u>		
Specimen #	Dino-Lite Measurement (mm)	Sensor Depth Measurement (mm)
16	2.279	5.660
17	2.317	5.698
18	2.309	5.690
19	2.190	5.571
20	2.246	5.627
21	2.187	5.568
22	2.380	5.761
23	2.198	5.579
24	2.070	5.451
25	2.183	5.564
26	2.007	5.388
27	2.231	5.612
28	2.536	5.917
29	2.183	5.564
N/A RT6 02/11/2021		

(Initial & Date) Executor: RT6 02/11/2021Executor: N/A RT6 02/11/2021(Print, Sign, & Date) Reviewer: Abigail Corn Abigail G 2/18/21

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## TP-90758 Results

Note: This page may be copied as necessary.

Sheet # 1 of 1Group DRP

Run # <u>1</u>		
A	B	C
Specimen #	Sensor Depth Measurement (mm)	Sensor Depth Results
1	5.74	<u>PASS</u> FAIL
2	5.72	<u>PASS</u> FAIL
3	5.70	<u>PASS</u> FAIL
4	5.38	<u>PASS</u> FAIL
5	5.62	<u>PASS</u> FAIL
6	5.56	<u>PASS</u> FAIL
7	5.64	<u>PASS</u> FAIL
8	5.53	<u>PASS</u> FAIL
9	5.56	<u>PASS</u> FAIL
10	5.53	<u>PASS</u> FAIL
11	5.41	<u>PASS</u> FAIL
12	5.58	<u>PASS</u> FAIL
13	5.50	<u>PASS</u> FAIL
14	5.62	<u>PASS</u> FAIL
15	5.62	<u>RTG 04/28/2021</u> <u>PASS</u> FAIL

Run # <u>1</u>		
A	B	C
Specimen #	Sensor Depth Measurement (mm)	Sensor Depth Results
16	5.66	<u>PASS</u> FAIL
17	5.70	<u>PASS</u> FAIL
18	5.69	<u>PASS</u> FAIL
19	5.57	<u>PASS</u> FAIL
20	5.63	<u>PASS</u> FAIL
21	5.57	<u>PASS</u> FAIL
22	5.76	<u>PASS</u> FAIL
23	5.58	<u>PASS</u> FAIL
24	5.45	<u>PASS</u> FAIL
25	5.56	<u>PASS</u> FAIL
26	5.39	<u>PASS</u> FAIL
27	5.61	<u>PASS</u> FAIL
28	5.92	<u>PASS</u> FAIL
29	5.56	<u>PASS</u> FAIL
<u>N/A RTG 02/11/2021</u>		<u>PASS</u> FAIL

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Rereview by Terrance Chan Tan CW 4/28/21

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**Defective Unit Sheet**

Note: This page may be copied as necessary

Sheet # 1 of 1  
Group DROP**Note:**Observations shall be approved by an Engineer.

Requirement Item number shall be the Item number of the acceptance criterion not met.

Run #	Specimen #	Noted at Section #	Requirement Item #	Observations
<div>(Sign &amp; Date) Entered by: _____</div> <div>(Sign &amp; Date) Approved by: _____</div>				
<div>(Sign &amp; Date) Entered by: _____</div> <div>(Sign &amp; Date) Approved by: _____</div>				
<div>(Sign &amp; Date) Entered by: _____</div> <div>(Sign &amp; Date) Approved by: _____</div>				

*N/A 2/18/21*

(Print, Sign, & Date) Reviewer: Abigail Corn Abigla 2/18/21

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## Protocol Notes Sheet

Note: This page may be copied as necessary.

Sheet # 1 of 1Group DROP**Note:**Deviations may be entered by an Executor and shall be approved by an Engineer.Test Method Losses and Anomalies shall be entered by an Executor and approved by a Quality Engineer.

Run #	Specimen #	Noted at Section #	Deviation	Anomaly	Test Method Loss	Note
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
(Sign & Date) Entered by:					(Sign & Date) Approved by:	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
(Sign & Date) Entered by:					(Sign & Date) Approved by:	
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
(Sign & Date) Entered by:					(Sign & Date) Approved by:	

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