CONFIDENTIAL

Project Number: 0875

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Project Description/Title:

Libra Wheelchair Cushion Testing for PDAC
Human Subject Test
Adjustable Skin Protection and Positioning (E2625)

(Revision 1)

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APPROVALS (Signature/Date)

EC Service, Inc: _____ 22 July 2014

Technician: Marianne Russon 22 July 2014

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1. **BACKGROUND:**
   1.1. This study consists of taking pressure maps of individuals sitting on Libra wheelchair cushions to demonstrate that the cushion performs better than standard reference foam. This information will be used to qualify the Libra cushion for reimbursement under CMS Reimbursement Policy for Wheelchair Cushions by submission of results to PDAC.

2. **EXECUTIVE SUMMARY:**
   2.1. The Libra cushion passes the requirements for an adjustable skin protection and positioning cushion (E2625) with a comparative pressure of 76.7% when new and 74.8% after aging.

3. **REFERENCES:**
   3.1. EC Service SOP 806.006 Pressure Mapping with Human Subject
   3.2. EC Service SOP 807.001 Conducting Human Subject Research
   3.3. ISO 554:1976E Standard Atmospheres for Conditioning and/or testing
   3.4. ISO Guide to Expression of Uncertainty in Measurement

4. **MATERIALS:**
   4.1. BodiTrak pressure mat, model BT 1510, serial number 8571, ECSR# 1304
   4.2. FSA Software Version 4.1.001
   4.3. Calibration Chamber
   4.4. Calibration Trays with Air Bladders
   4.5. Air hose system
   4.6. Mercury Manometer, mfg by ADC, 0-300 mmHg, S/N 007646
   4.7. Computer
   4.8. Invacare Matrx Libra with accessories, 16x16 (new), ECSR# 1249
   4.9. Invacare Matrx Libra 16x16 with accessories (aged – see 7.1) mfg 06-03-14, ECSR 1249
   4.10. Invacare Matrx Libra 17x17 with accessories (new), mfg 05-03-14, ECSR# 1250
   4.11. Invacare Matrx Libra 17x17 with accessories (aged – see 7.1), ECSR# 1250
   4.12. Invacare Matrx HR42250 foam, 18”x18”x3”, 25% IFD of 45, Density 2.7 lbs/cu
   4.13. Tapered wedge 1487155, ECSR# 1271
   4.14. Large pommel 1487162, ECSR#1271

5. **VOLUNTEERS:**
   5.1. Volunteer 1: Age 55, 6 feet 0 inches, 165 lbs, paraplegic, insensate, tested 23 June 2014
   5.2. Volunteer 2: Age 50, 6 feet 2 inches, 185 lbs, paraplegic, some sensation, tested 26 June 2014
   5.3. Volunteer 3: Age 60, 5 feet 11 inches, 160 lbs, T12L1 paraplegic, left leg amputated above the knee, insensate, tested 23 June 2014
   5.4. Volunteer 4: Age 40, 5 feet 4 inches, 135 lbs, T11/T12 paraplegic, insensate, tested 30 June 2014
   5.5. Volunteer 5: Age 41, 6 feet 1 inch, 175 lbs, L1 paraplegic, insensate, tested 30 June 2014
   5.6. Volunteer 6: Age 29, 6 feet 2 inches, 210 lbs, paraplegic, insensate, tested 01 July 2014
   5.7. Volunteer 7: Age 24, 5 feet 11 inches, 156 lbs, ambulatory, sensate, tested 10 July 2014
   5.8. Volunteer 8: Age 27, 5 feet 0 inches, 105 lbs, ambulatory, sensate, tested 11 & 14 July 2014

5.9. Volunteer 9: Age 33, 6 feet 0 inches, 245 lbs, ambulatory, sensate, tested 14 July 2014
5.10. Volunteer 10: Age 33, 6 feet 2 inches, 200 lbs, paraplegic, insensate, tested 15 July 2014

6. TEST ENVIRONMENT:

6.1. An environment with ambient temperature of 23 +/-2 °C and relative humidity 50% +/- 5% as specified in ISO 554-1976(E).

7. METHOD:

7.1. Simulated Aging of Cushions

7.1.1. Two cushions of each size were provided by the manufacturer. One of each size underwent simulated aging. The cushions were cyclically loaded (without gel inserts) 51,500 cycles at 70° C, Gel inserts were aged at 70° C for 11 days.

7.2. Calibration and Validation

7.2.1. The pressure map was calibrated per manufacturer's software.
7.2.2. While still in the calibration chamber, the mat was validated by increasing the pressure to 50 mmHg of mercury. The software was allowed to record for 120 seconds. The recording was stopped and the last frame exported for analysis.
7.2.3. The pressure was increased to 100 mmHg. The software was allowed to record for 120 seconds. The recording was stopped and the last frame exported for analysis.
7.2.4. Testing proceeded when it was verified that the values were within ± 10% of full scale.
7.2.5. Percent error of measurement is reported in 11.2 and 11.3.

7.3. Test Set Up

7.3.1. Instrumentation options were selected so that the sensor outputs were not averaged.
7.3.2. Instrument Sampling was set to at least one pressure sensor array data set per second (60 Hz).
7.3.3. Determined the appropriate size cushion for the user. The cushion was adjusted to achieve the best fit possible using accessories as necessary.
7.3.4. The cushion being tested was placed into the wheelchair.
7.3.5. The pressure map was overlaid on the cushion, removing any wrinkles.

7.4. Testing

7.4.1. The subject transferred onto the cushion/pressure map and the technician began recording the pressure map.
7.4.2. Subjects were positioned in their typical posture as determined by query and independent facility judgment.
7.4.3. Any folds or wrinkles in the pressure map were removed. With the map properly situated under the subject, the ischial tuberosities and sacrum/coccyx were identified by palpation.
7.4.4. Data was recorded for 120 seconds. The data from the last frame was exported for analysis.
7.4.5. The subject transferred off the cushion and the cushion was allowed to recover for 120 seconds.
7.4.6. Repeated Steps 7.3.1 to 7.4.5 one each surface for a total of five trials each. After each trial the cushion was "reset" by flattening or kneading with hands.
7.4.7. Each subject was tested on new and aged cushions, and the reference foam.

8. CALCULATIONS:

8.1. **Peak Pressure Index:** For each test, the cell in the sacro-ischial zone with the highest pressure is identified. The greatest sum of pressures in the identified cell and adjacent cells is determined. (For a pressure map with a cell size of 2.5 sq cm, a 2 by 2 array is used). The peak pressure index (PPI) is the average of the cells with the greatest sum of pressures. The average of the five trials is calculated for each subject.

8.1.1. To determine if the minimum performance characteristics specified for a particular type of cushion is met, the average PPI for 10 subjects on the test cushion and the average PPI for the 10 subjects on the reference foam is calculated. The average PPI on the test cushion is divided by the average PPI on the reference foam cushion and multiplied by 100 to give the percentage comparison of peak pressure indexes. For adjustable/skin protecting cushions the comparative values must be less than 85%.

8.2. **Peak Pressure:** The highest recorded reading on the pressure map or within a specified zone.

8.3. **Average Pressure:** The average of the entire pressure map or zone for sensors with a pressure greater than or equal to 5 mmHg.

8.4. **Contact Area:** The area with pressure readings greater than or equal to 10 mmHg. The Contact Area was calculated from:

$$\mathbf{CA = (A \times N_5) / N_{Total}};$$

Where
CA = contact area cm^2
A = area of pressure mat containing sensors cm^2
N_{Total} = total number of sensors in mat (or zone)
N_5 = number of sensors with pressure readings greater than or equal to 5 mm Hg.

9. RESULTS:

9.1. Individual pressure maps can be seen in the Appendix.

Table 1 Peak pressure index (mmHg). Data for individual volunteers is calculated at a 95% confidence interval.

Volunteer	New	Aged	Reference Foam
1	197.7 ± 25.5	181.1 ± 14.1	221.5 ± 22.4
2	111.1 ± 2.1	111.2 ± 8.4	150.1 ±13.8
3	138.7 ± 9.2	118.7 ± 8.4	182.5 ± 19.7
4	90.6 ± 13.6	92.7 ± 3.8	140.0 ± 41.0
5	136.9 ± 12.7	143.4 ± 18.2	200.8 ± 26.6
6	103.1 ± 4.6	94.0 ± 5.9	123.2 ± 14.8
7	103.9 ± 5.5	116.4 ± 12.4	149.0 ± 10.7
8	80.2 ± 4.2	91.4 ± 12.1	83.1 ± 3.0
9	79.7 ± 7.6	84.1 ± 3.2	96.9 ± 6.6
10	118.1 ± 7.6	97.7 ± 13.5	165.4 ± 30.3
Average	116.0	113.1	151.2
% difference	76.7%	74.8%	

Table 2 Peak pressure (mmHg). Data is calculated at a 95% confidence interval.

Volunteer	New	Aged	Reference Foam
1	278.8 ± 37.9	226.6 ± 22.4	287.7 ± 24.2
2	120.4 ± 5.6	123.3 ± 8.7	168.3 ± 5.6
3	163.3 ± 13.3	158.3 ± 23.3	257.8 ± 29.3
4	112.1 ± 9.9	111.5 ± 4.4	197.0 ± 78.3
5	165.0 ± 21.1	205.1 ± 15.8	267.7 ± 39.4
6	123.4 ± 11.9	116.5 ± 12.0	175.2 ± 61.3
7	133.6 ± 10.0	146.7 ± 18.1	163.7 ± 10.4
8	98.9 ± 8.6	105.0 ± 11.8	107.1 ± 4.3
9	88.6 ± 7.9	96.2 ± 10.8	1002.3 ± 7.2
10	149.0 ± 13.7	110.66 ± 11.4	209.6 ± 37.2

Table 3 Average pressure (mmHg). Data is calculated at a 95% confidence interval.

Volunteer	New	Aged	Reference Foam
1	53.0 ± 2.8	50.4 ± 6.1	55.7 ± 2.1
2	55.0 ± 3.4	53.4 ± 2.9	61.2 ± 3.0
3	50.4 ± 2.9	45.9 ± 3.3	54.4 ± 4.8
4	38.7 ± 3.4	40.2 ± 0.8	45.4 ± 5.0
5	56.7 ± 1.7	58.8 ± 5.0	60.5 ± 4.0
6	55.9 ± 3.0	56.2 ± 4.7	51.3 ± 5.5
7	56.3 ± 4.0	60.9 ± 4.3	62.7 ± 2.3
8	29.3 ± 1.5	31.8 ± 1.5	33.9 ± 2.4
9	48.5 ± 4.2	18.4 ± 2.1	50.8 ± 4.1
10	41.0 ±3.6	37.0 ± 2.3	45.1 ± 4.9

Table 4 Contact area (cm^2).). Data is calculated at a 95% confidence interval.

Volunteer	New	Aged	Reference Foam
1	1251.6 ± 43.6	1304.5 ± 51.4	1349.7 ± 41.1
2	1449.0 ± 24.5	1474.8 ± 57.8	1553.6 ± 26.6
3	1383.2 ± 57.9	1361.3 ± 53.4	1357.42 ± 31.1
4	1467.1 ± 41.3	1357.4 ± 66.0	1476.1 ± 28.1
5	1423.2 ± 25.5	1452.9 ± 34.0	1507.1 ± 25.1
6	1478.7 ± 58.6	1416.8 ± 14.8	1574.2 ± 17.0
7	1400.0 ± 43.1	1371.6 ± 38.1	1486.5 ± 7.6
8	1163.9 ± 28.7	1171.6 ± 18.6	1169.0 ± 46.9
9	1452.9 ± 26.3	1531.61 ± 19.0	1541.9 ± 48.5
10	1406.45 ± 86.9	1467.01 ± 40.1	1460.7 ± 31.1

10. **CONCLUSIONS:**

10.1. The Libra cushion passes the requirements for an adjustable skin protection and positioning cushion (E2625) with a comparative pressure of 76.7% when new and 74.8% after aging (Table 1).

11. **STATEMENT OF UNCERTAINTY**

11.1. The BodiTrak has a sensor size of 25.4mm and a sensing area of 455 mm x455 mm. It was calibrated to 300 mmHg.

11.2. The BodiTrak was calibrated on 19 June 2014. Percent error of measurement at 50 mmHg was11.0% ± 0.9%. Percent error of measurement at 100 mmHg was 7.5% ± 0.7%

11.2.1. The BodiTrak was calibrated again on 11 July. Percent error of measurement at 50 mmHg was 4.9% ± 0.4%. Percent error of measurement at 100 mmHg was 7.0% ± 0.6%.

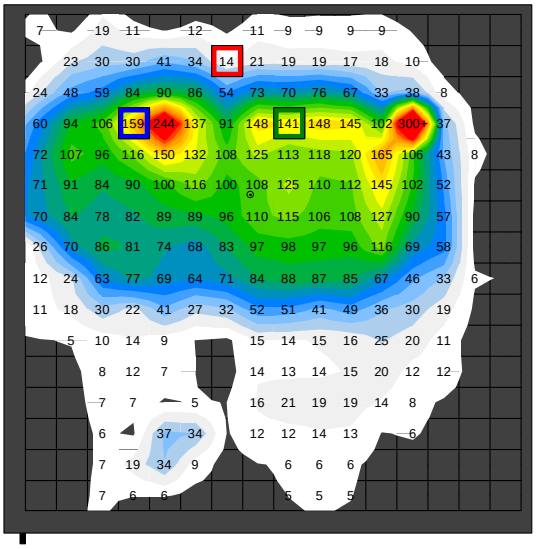
11.3. All data was calculated to a 95% confidence interval.

- END -

APPENDIX

Volunteer 1, New Cushion

Trial 1



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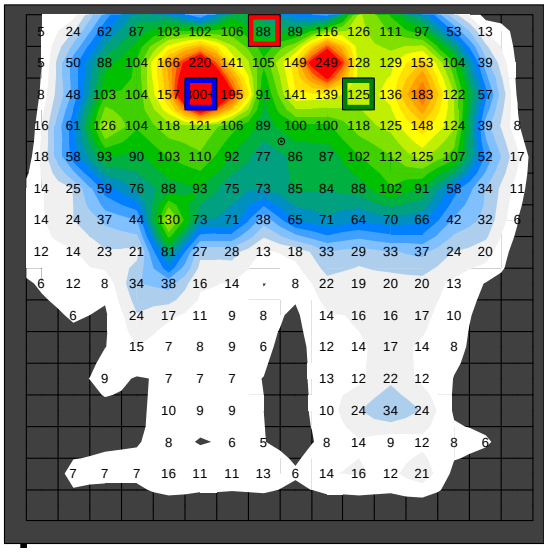

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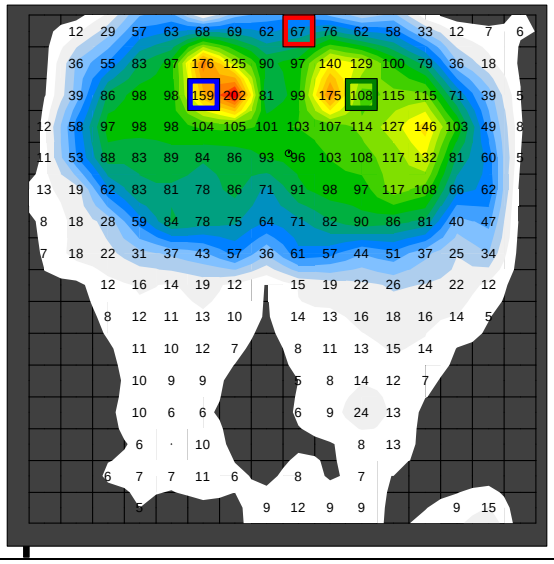

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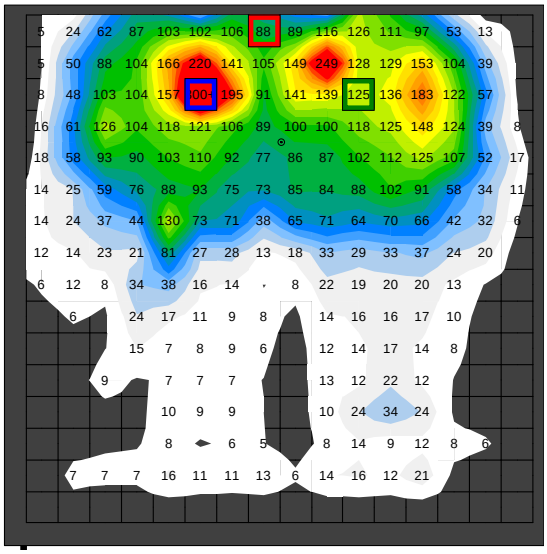

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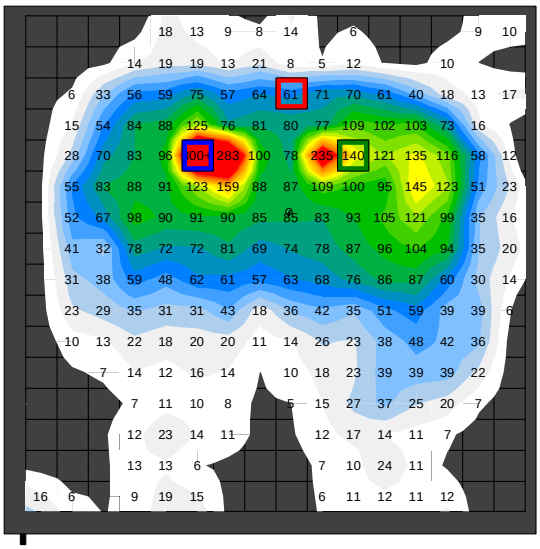

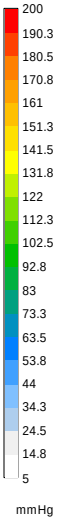

Volunteer 1, Aged Cushion

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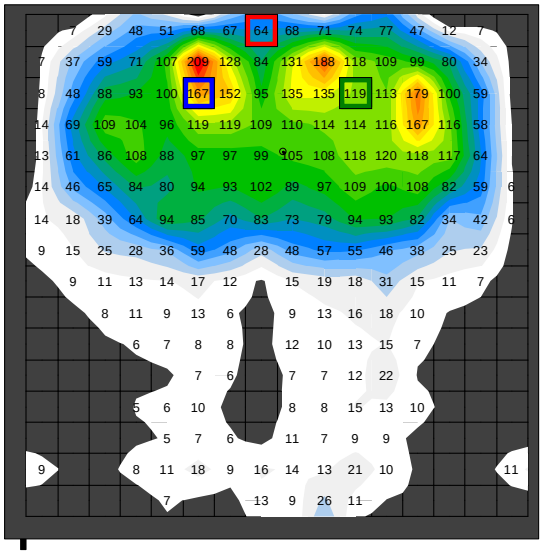

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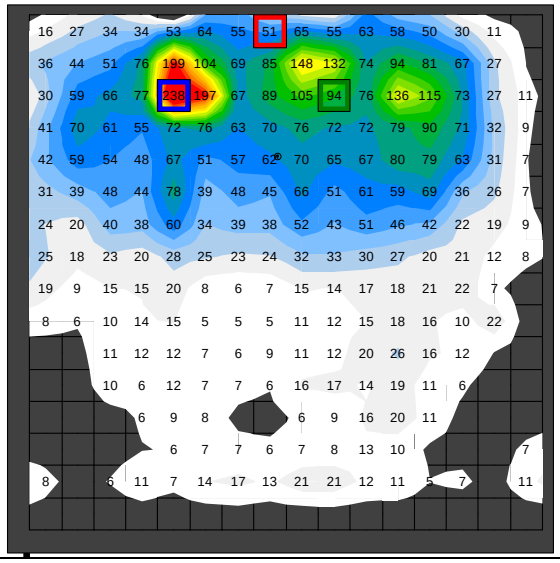

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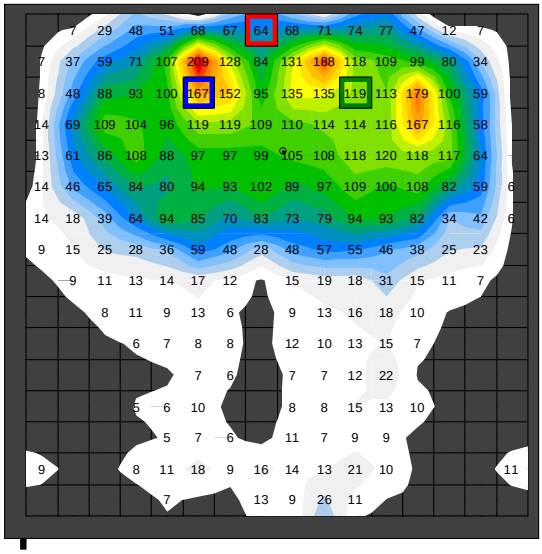

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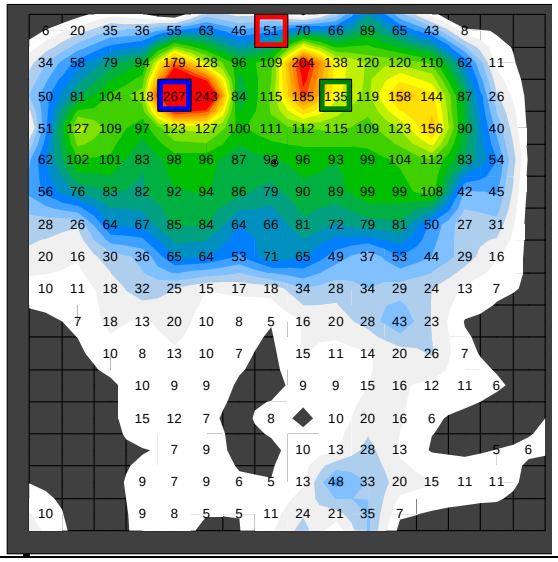

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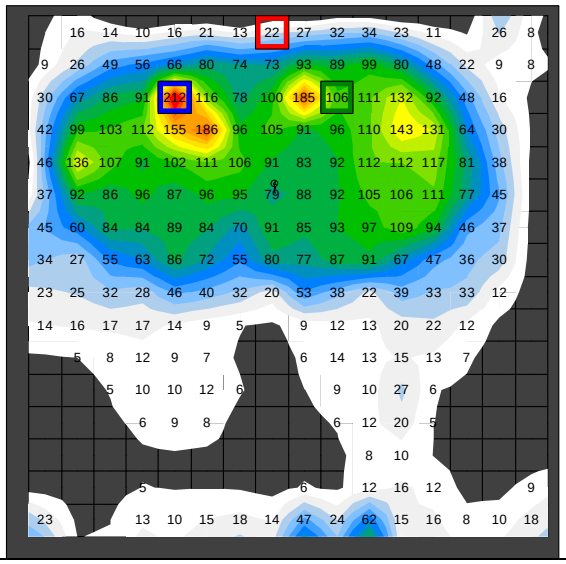
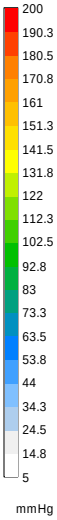
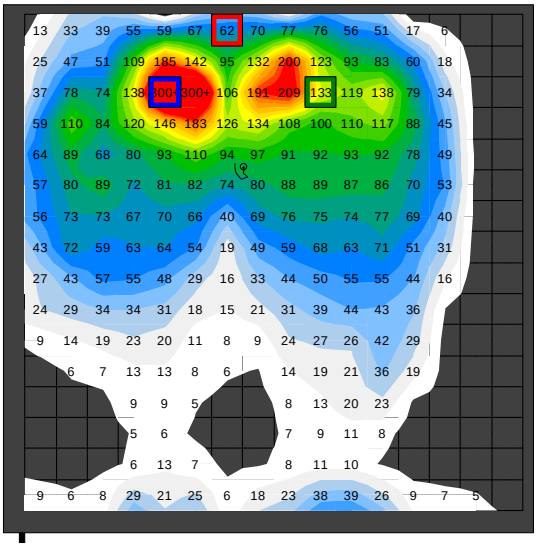




Volunteer 1, Reference Foam

Trial 1



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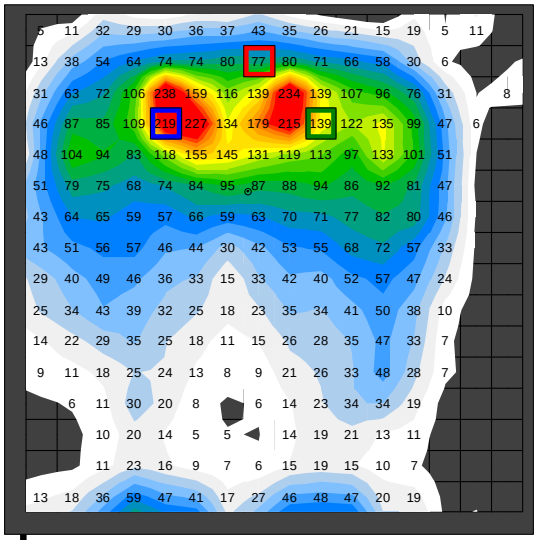

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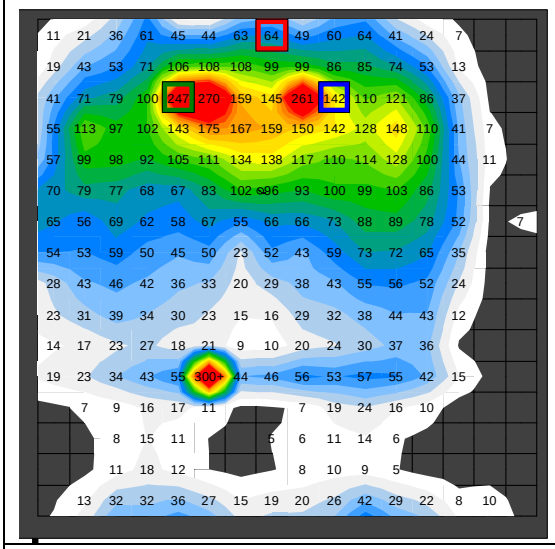

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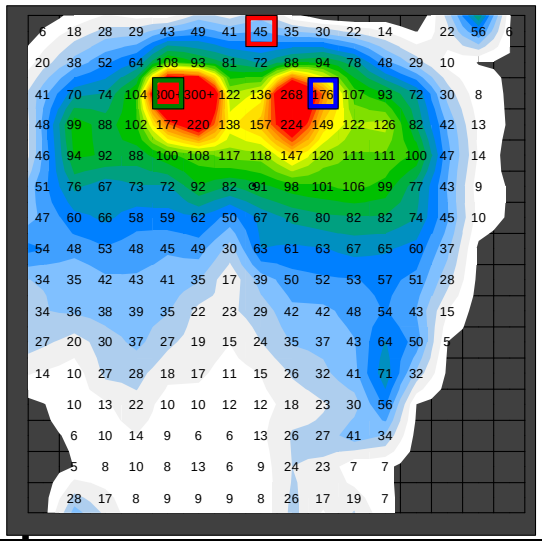

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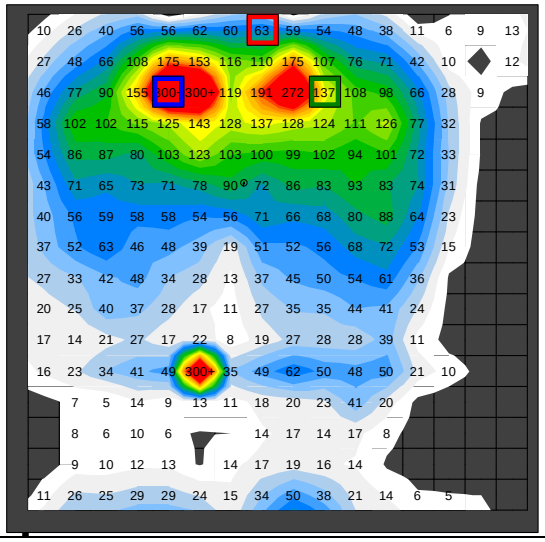

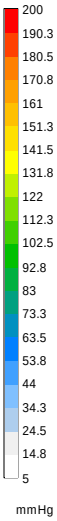

Volunteer 2, New Cushion

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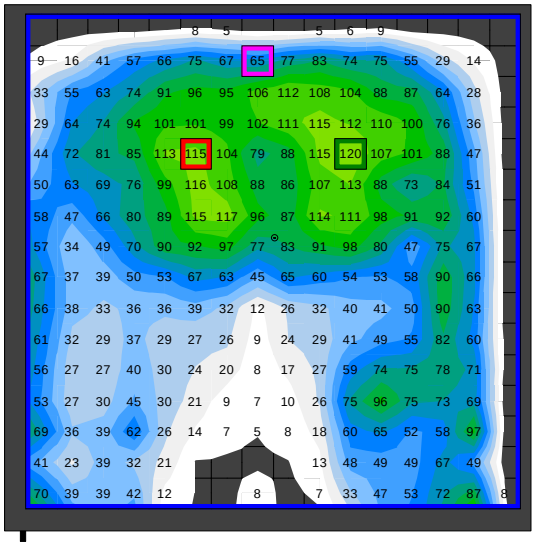

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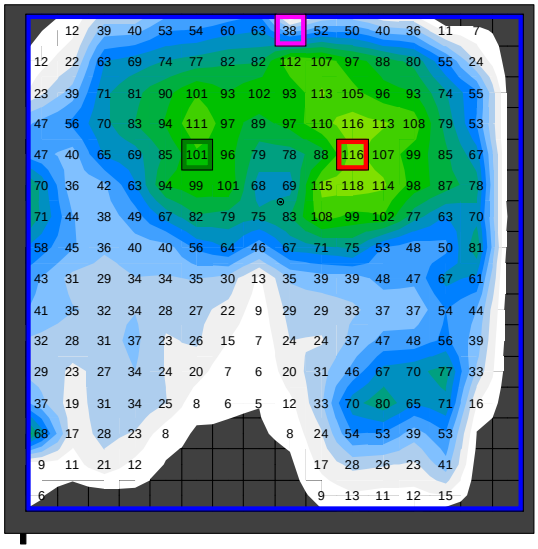

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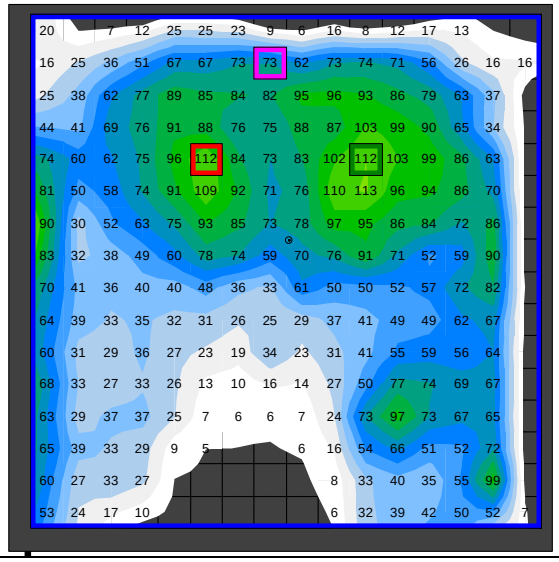

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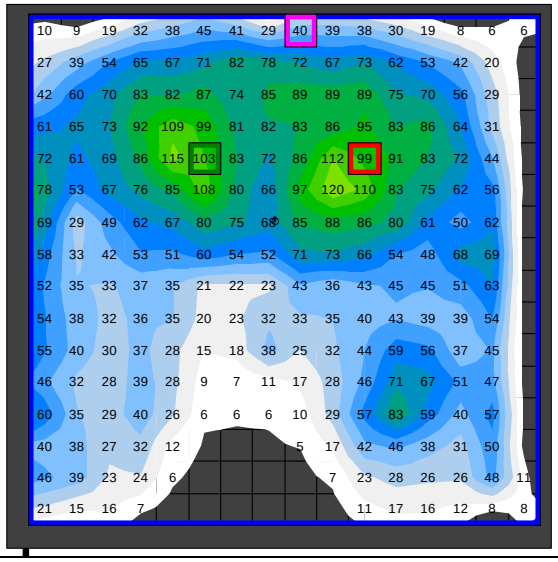

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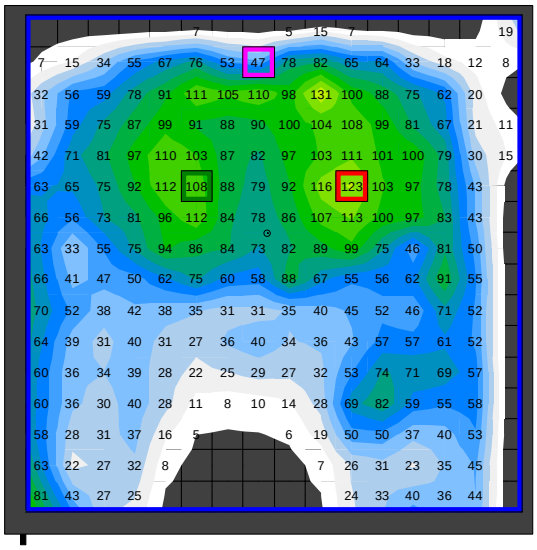
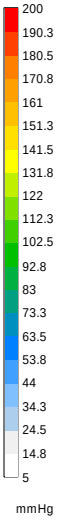
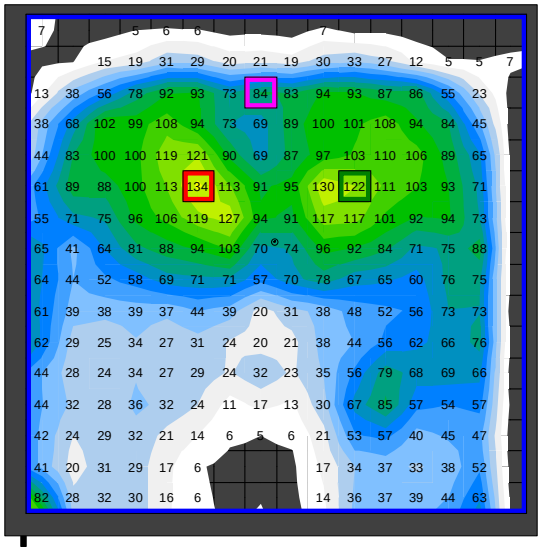




Volunteer 2, Aged Cushion

Trial 1



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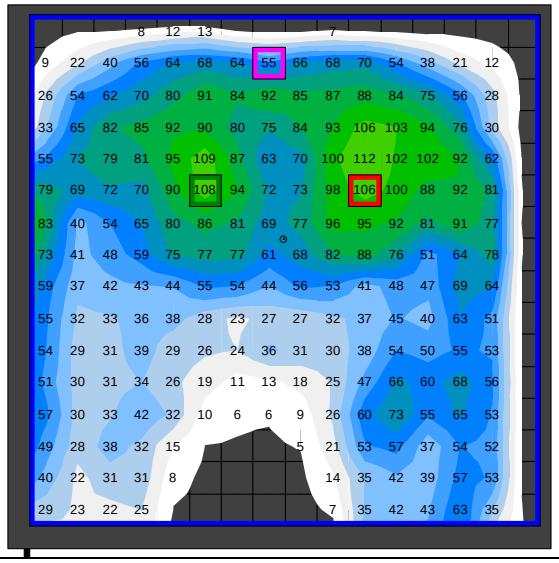

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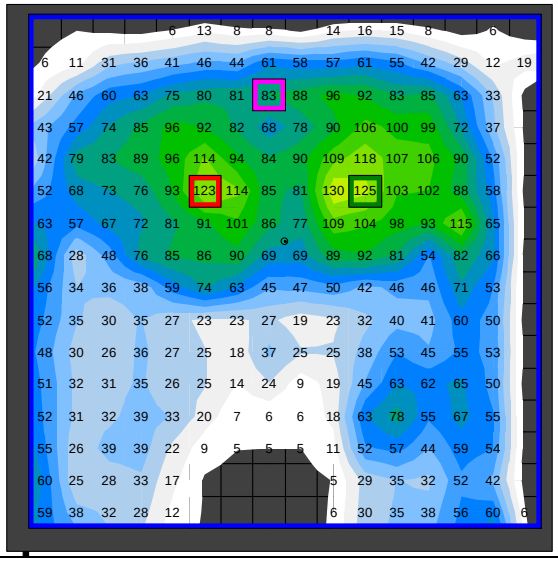

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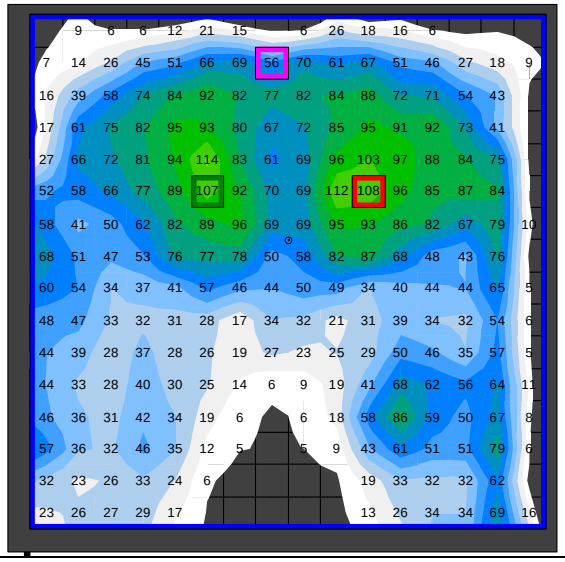

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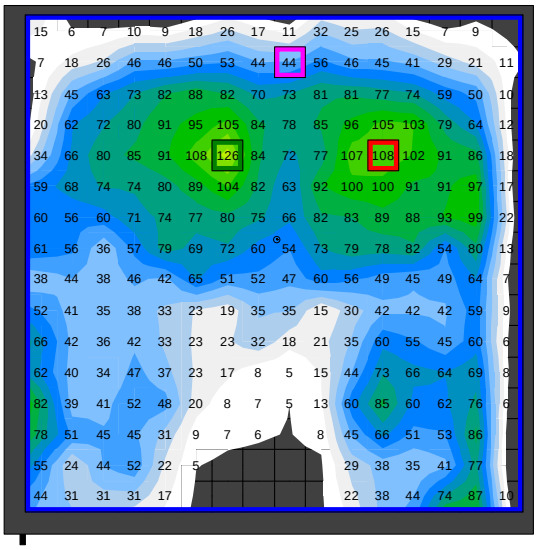

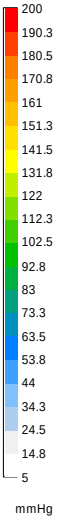

Volunteer 2, Reference Foam

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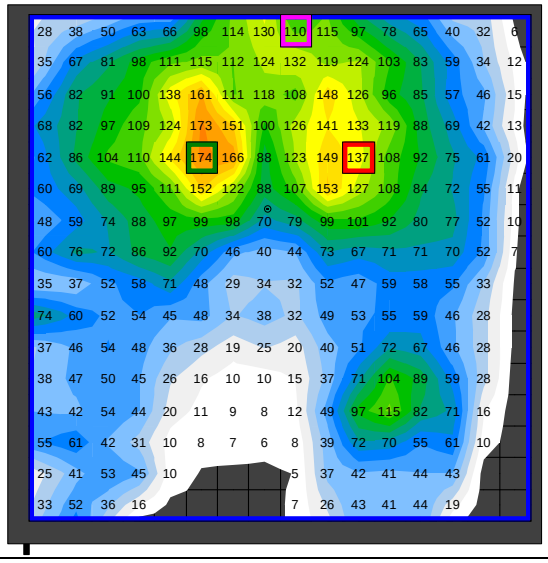

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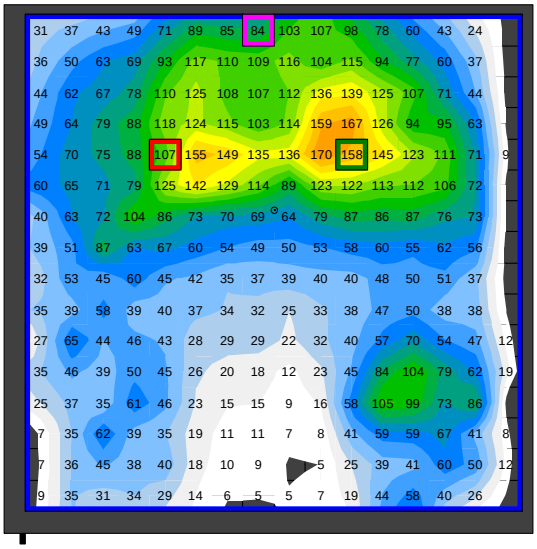

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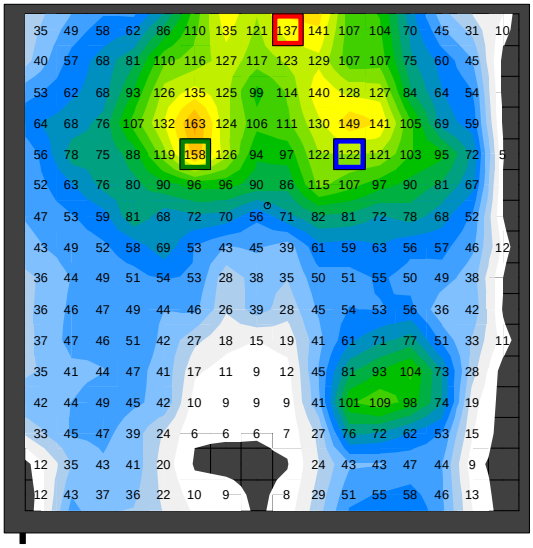
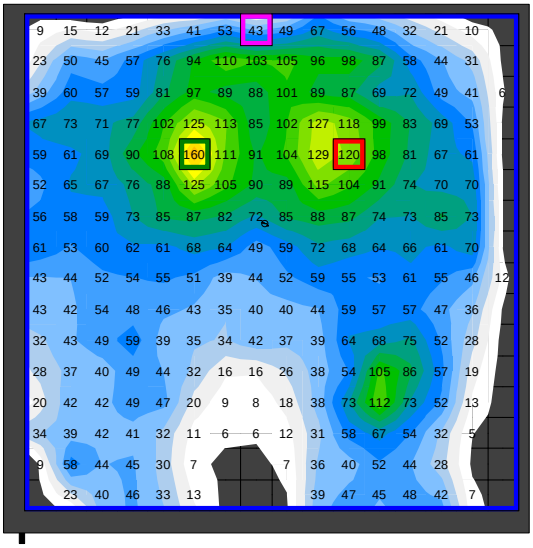
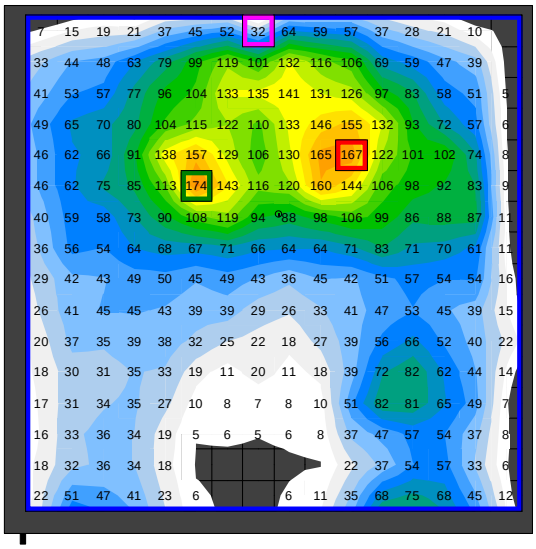
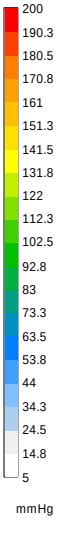


Trial 5



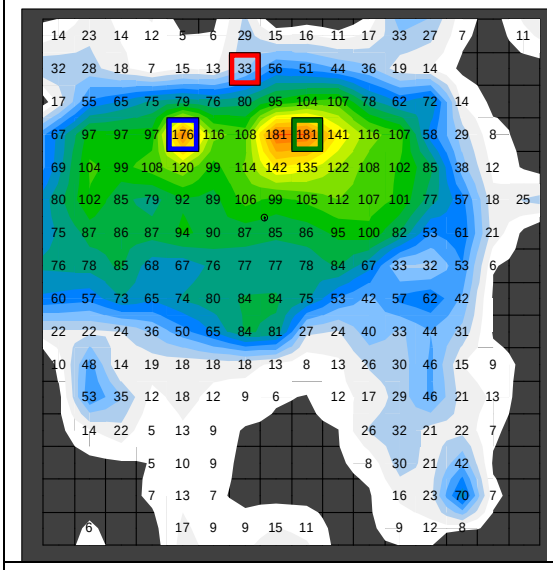
Trial 3



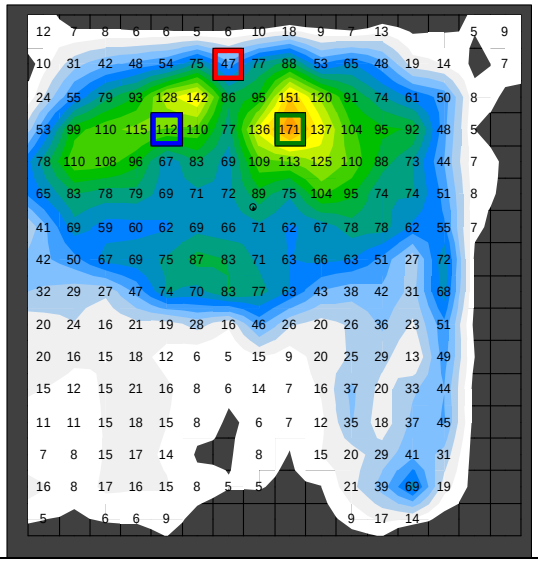


Volunteer 3, New Cushion

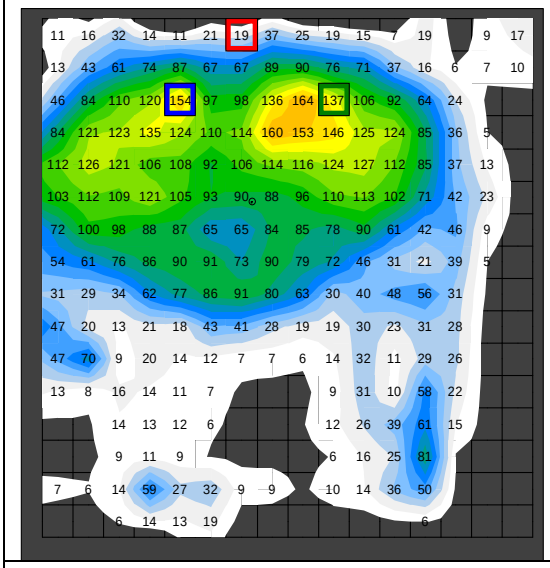
Trial 1



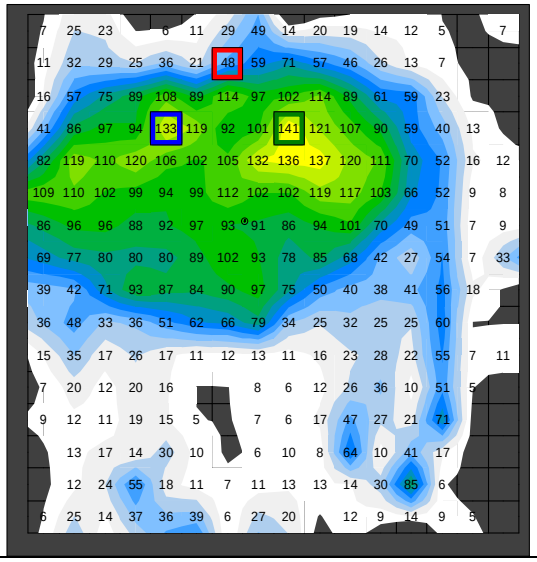
Trial 4



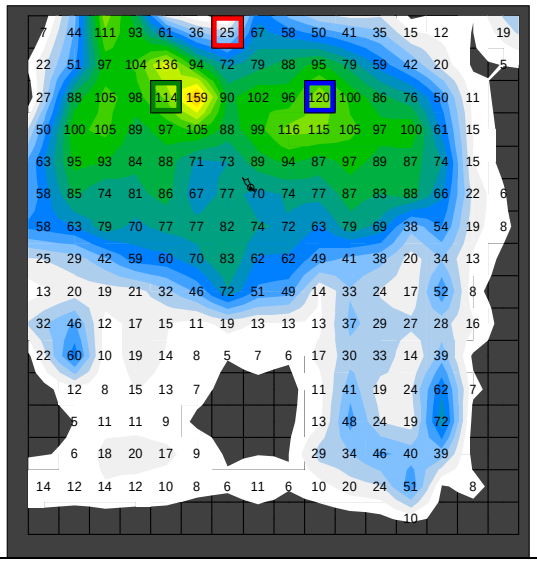
Trial 2

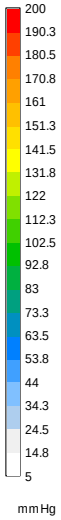


Trial 5



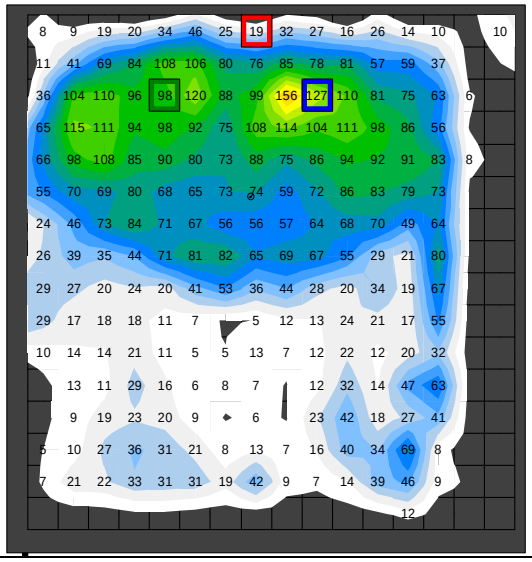
Trial 3



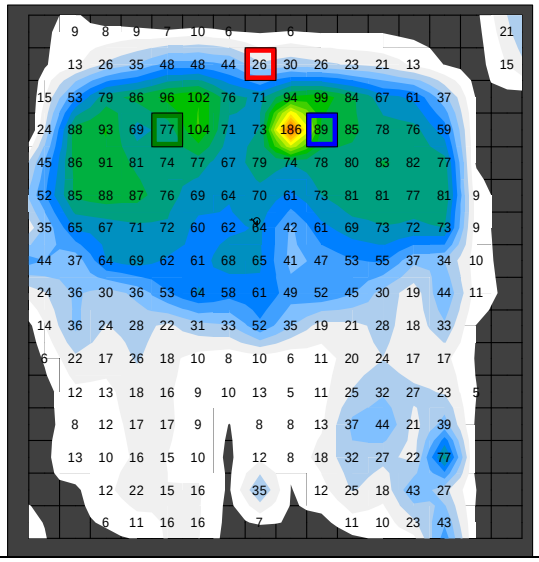


Volunteer 3, Aged Cushion

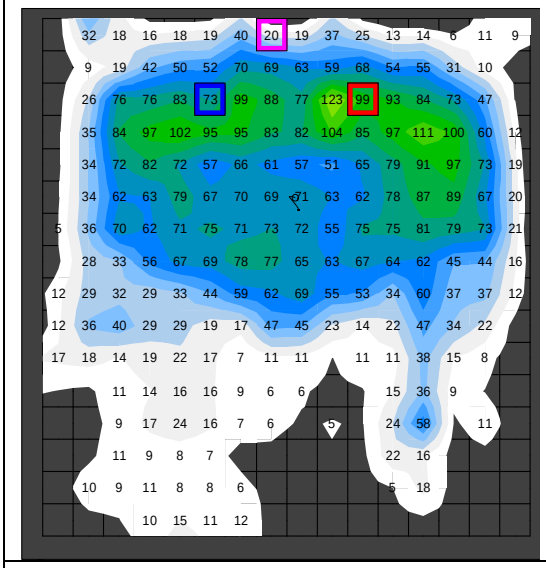
Trial 1



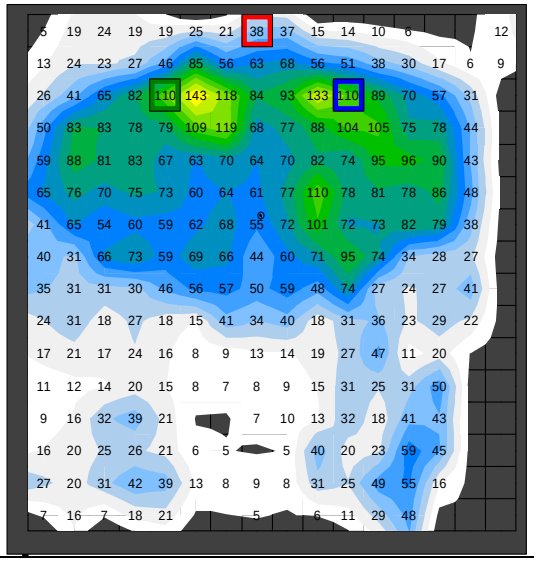
Trial 4



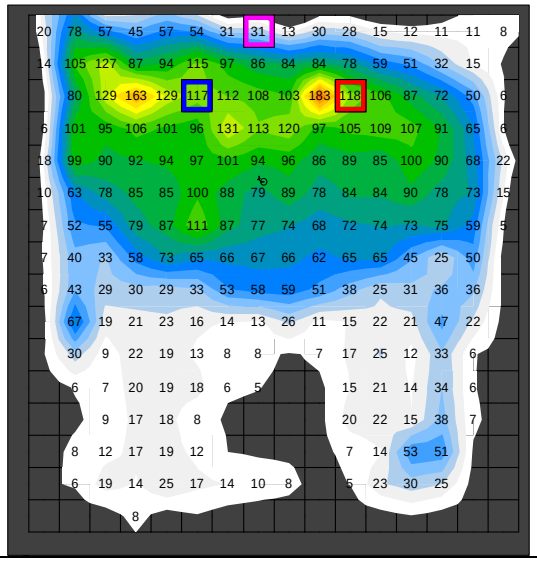
Trial 2

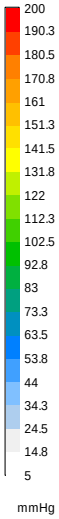


Trial 5



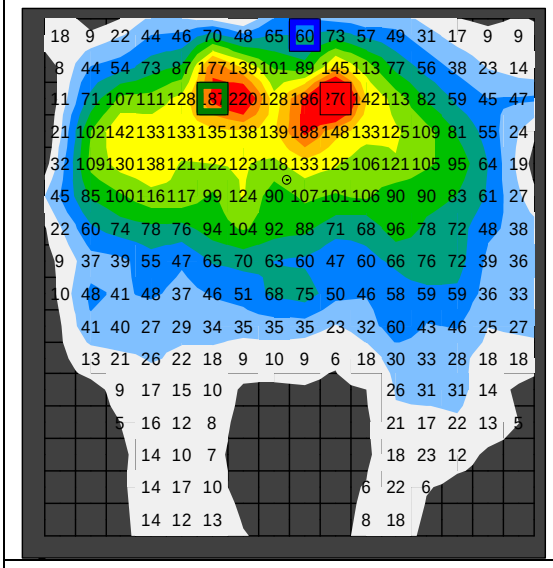
Trial 3



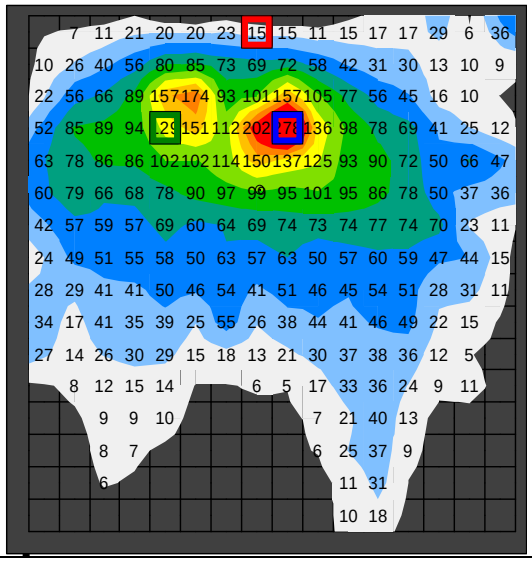


Volunteer 3, Reference Foam

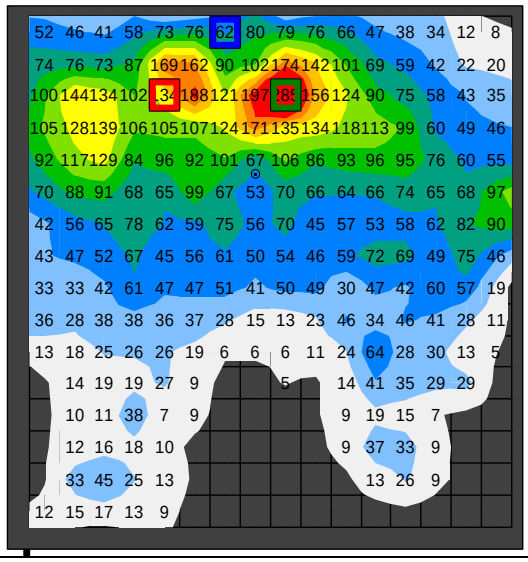
Trial 1



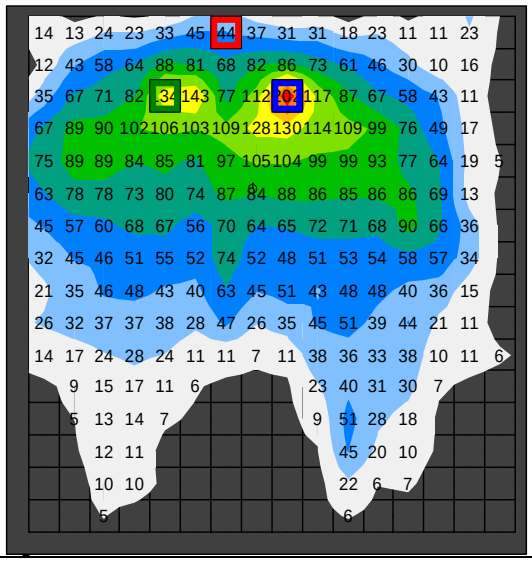
Trial 4



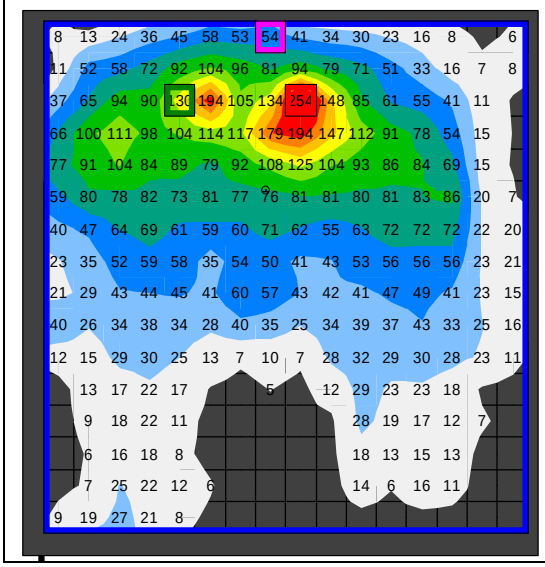
Trial 2

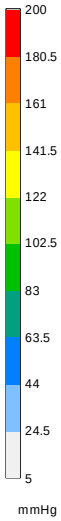


Trial 5



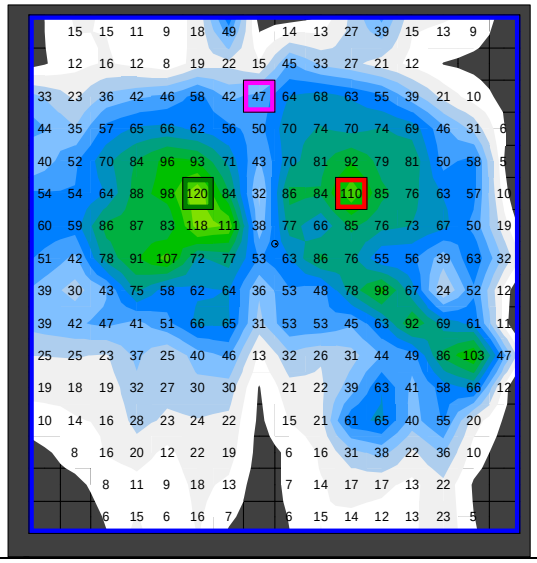
Trial 3



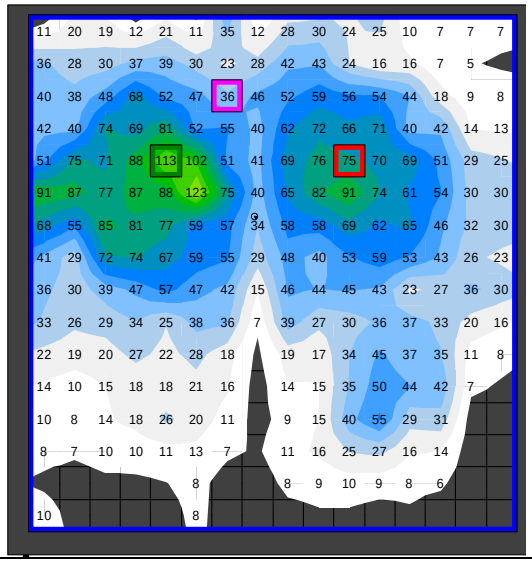


Volunteer 4, New Cushion

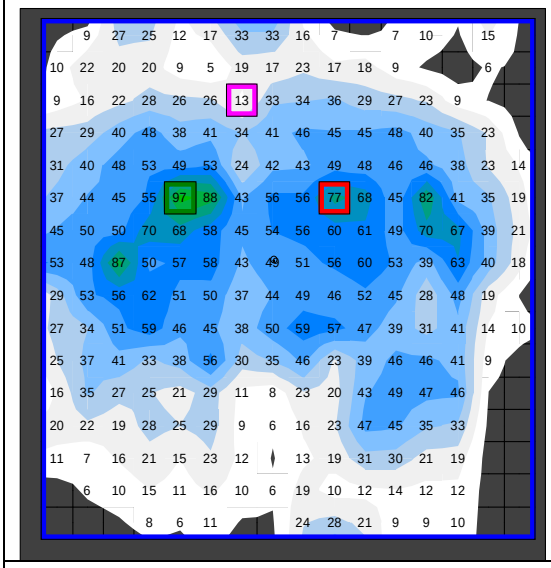
Trial 1



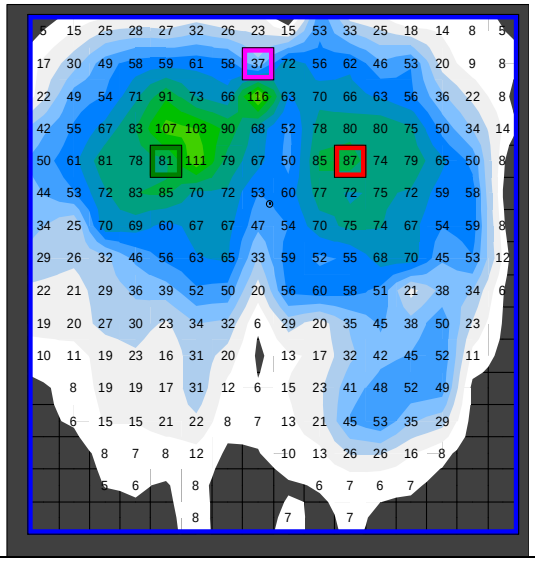
Trial 4



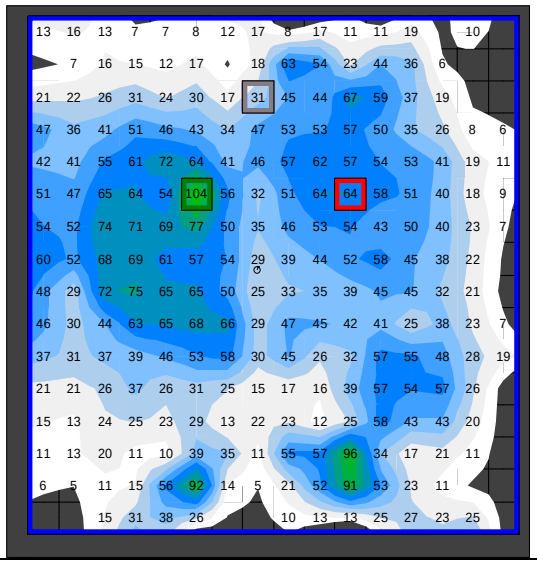
Trial 2

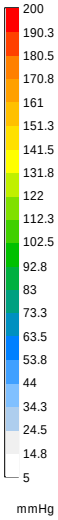


Trial 5



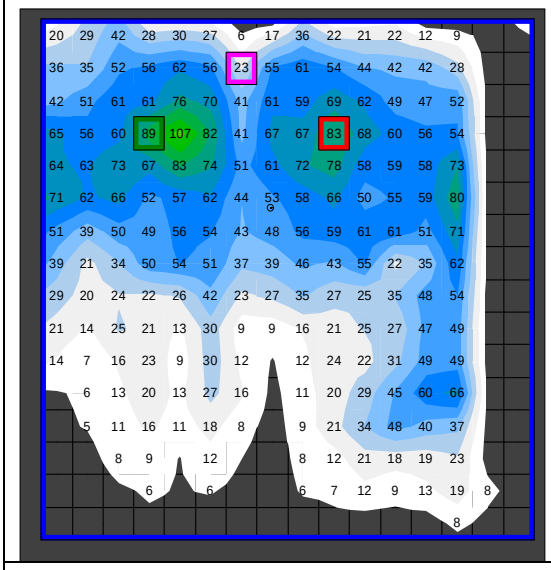
Trial 3



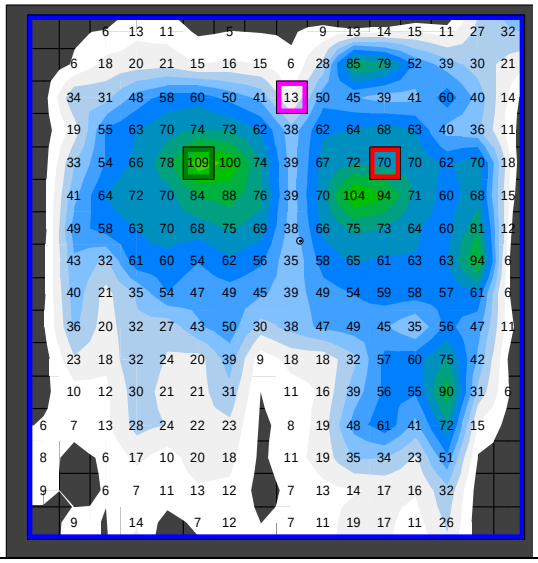


Volunteer 4, Aged Cushion

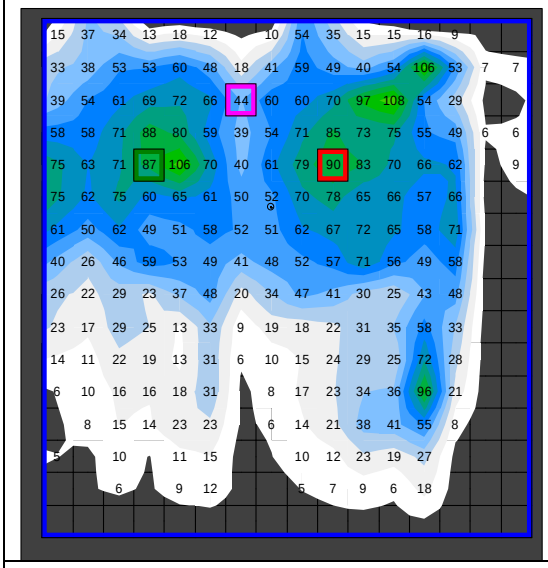
Trial 1



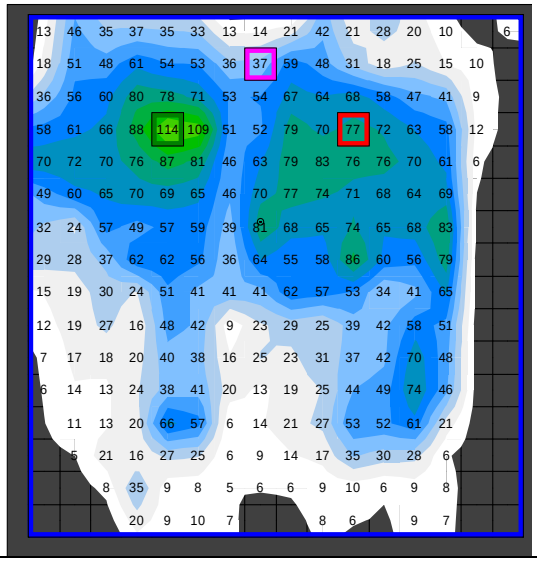
Trial 4



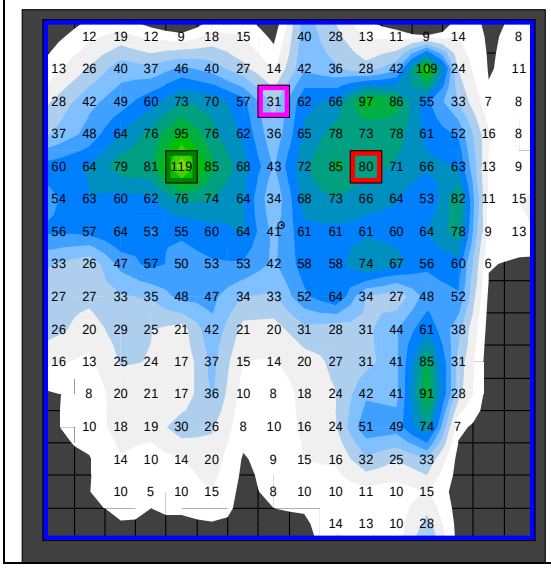
Trial 2

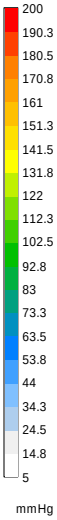


Trial 5



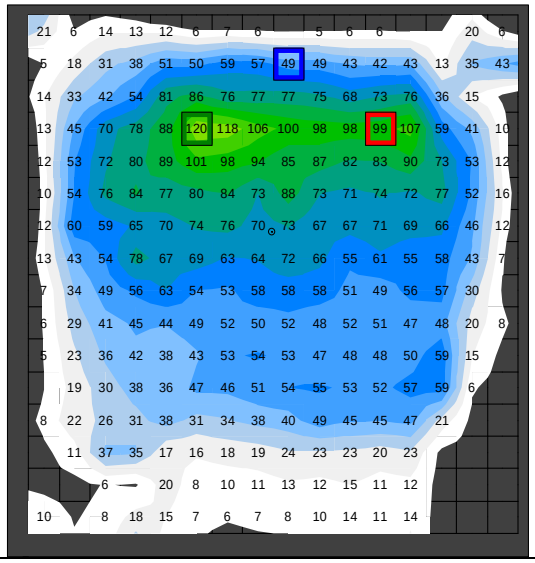
Trial 3



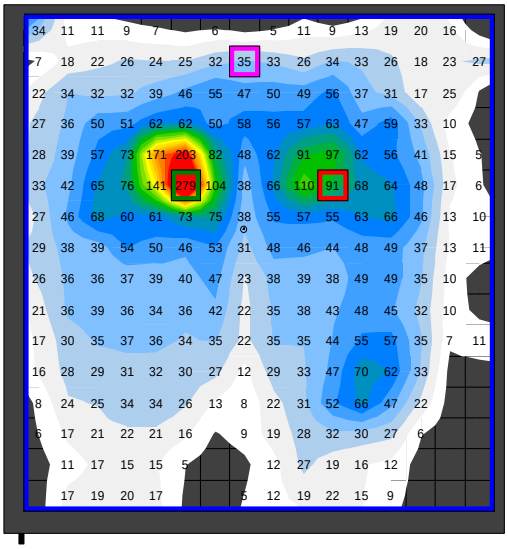


Volunteer 4, Reference Foam

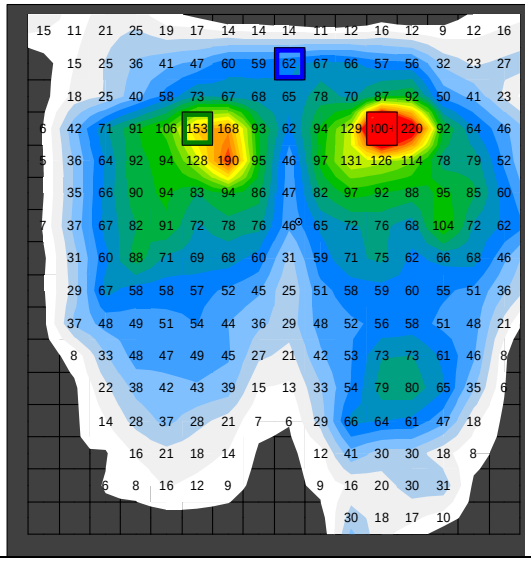
Trial 1



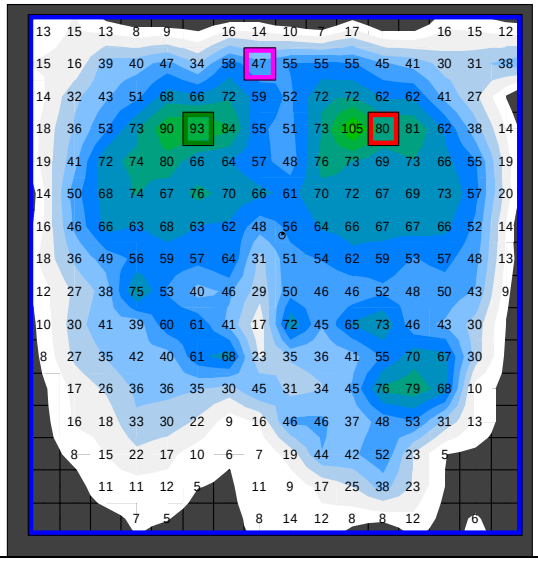
Trial 4



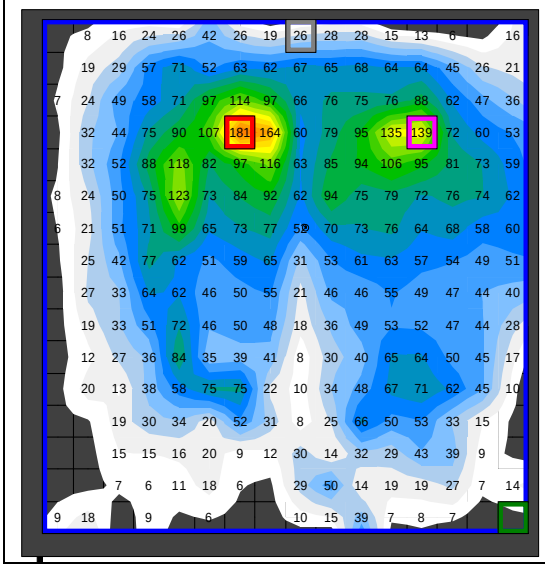
Trial 2

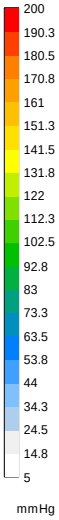


Trial 5



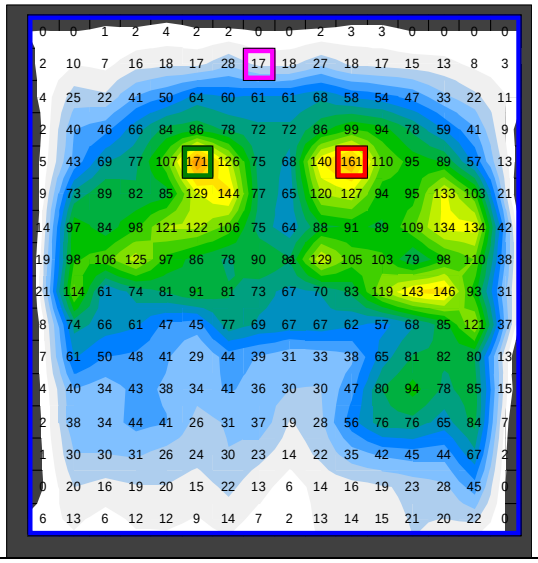
Trial 3



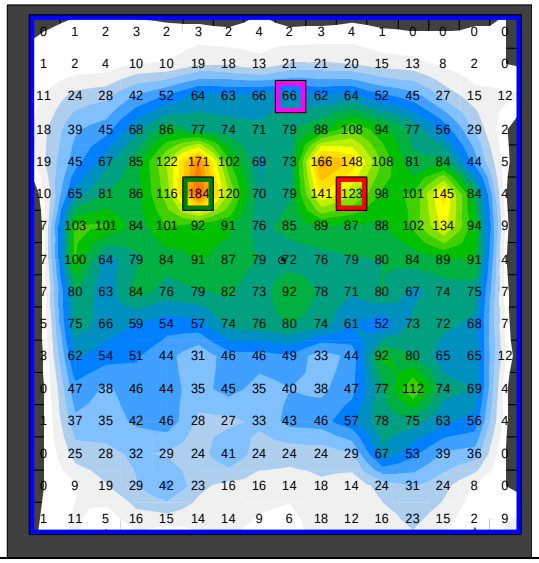


Volunteer 5, New Cushion

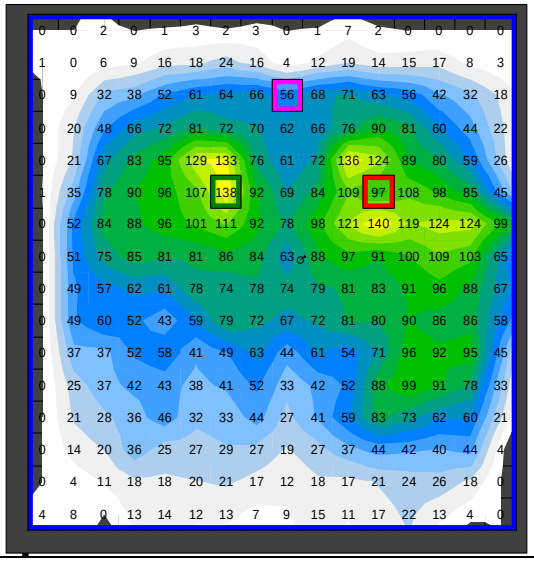
Trial 1



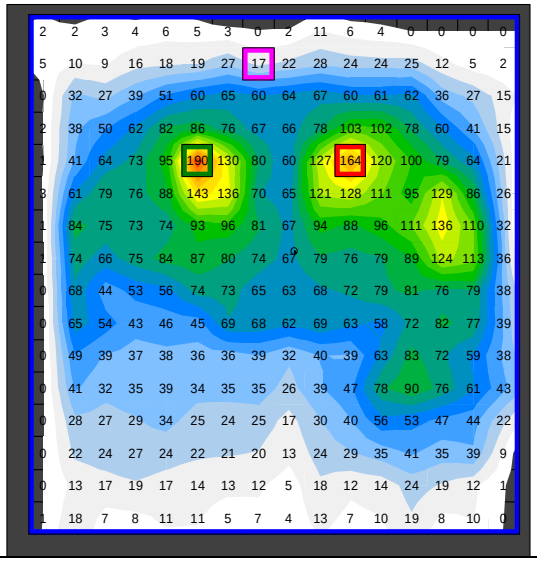
Trial 4



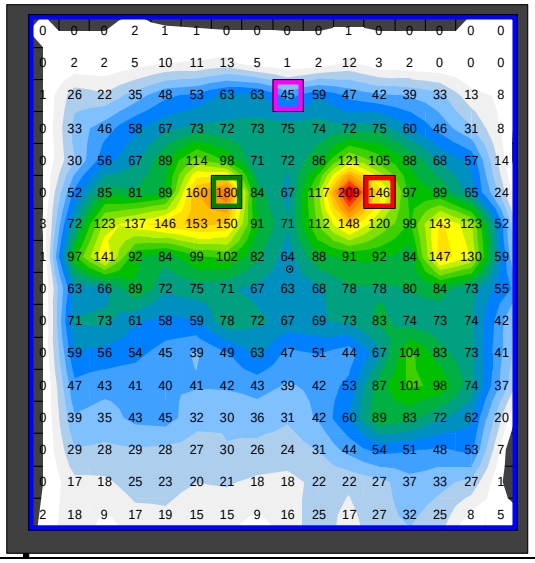
Trial 2

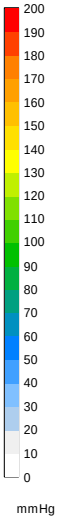


Trial 5



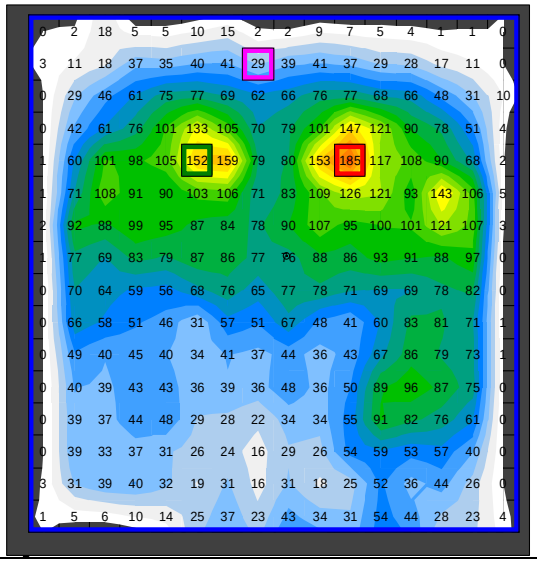
Trial 3



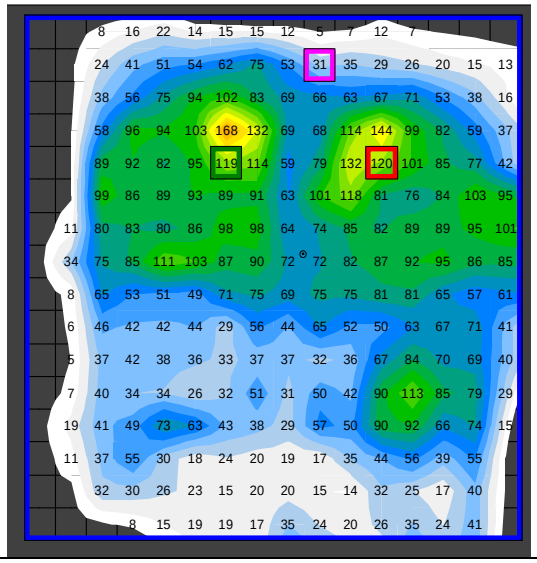


Volunteer 5, Aged Cushion

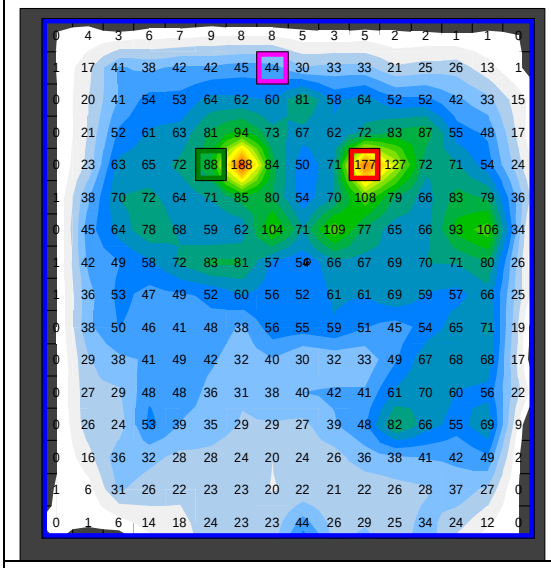
Trial 1



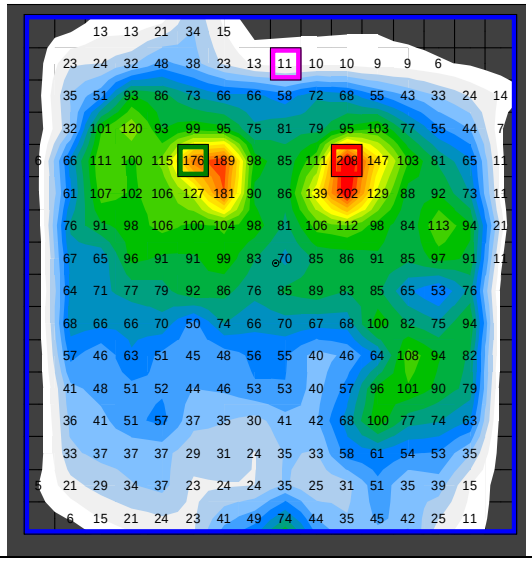
Trial 4



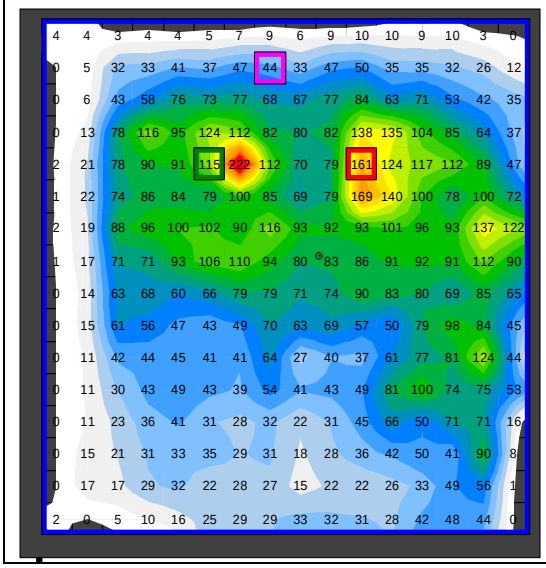
Trial 2

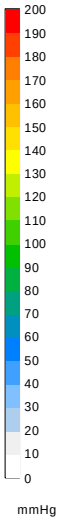


Trial 5



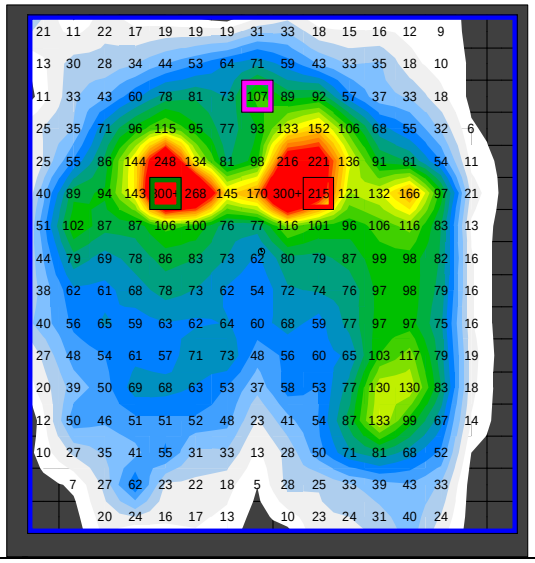
Trial 3



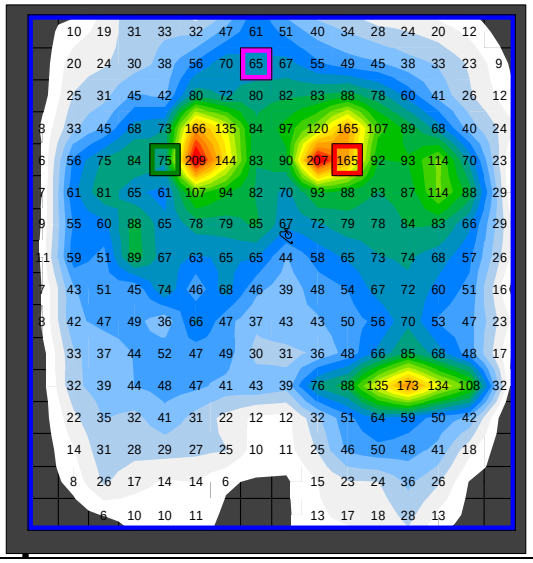


Volunteer 5, Reference Foam

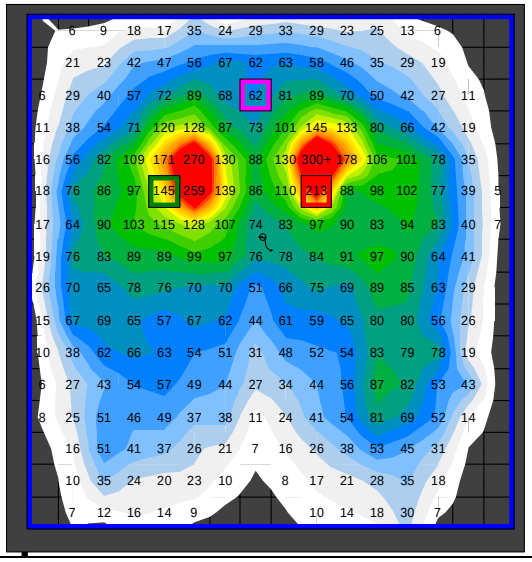
Trial 1



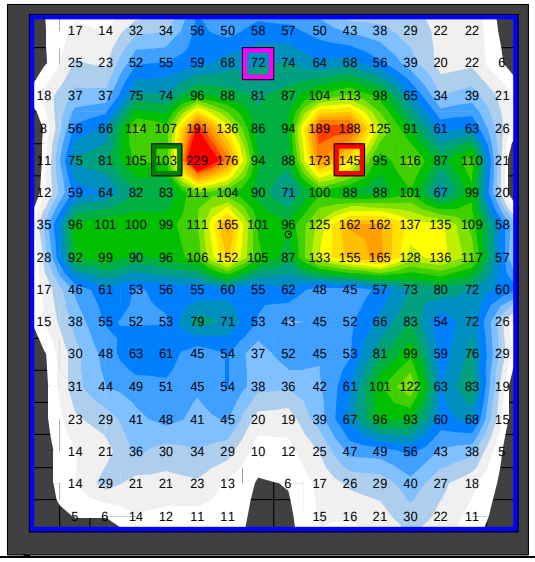
Trial 4



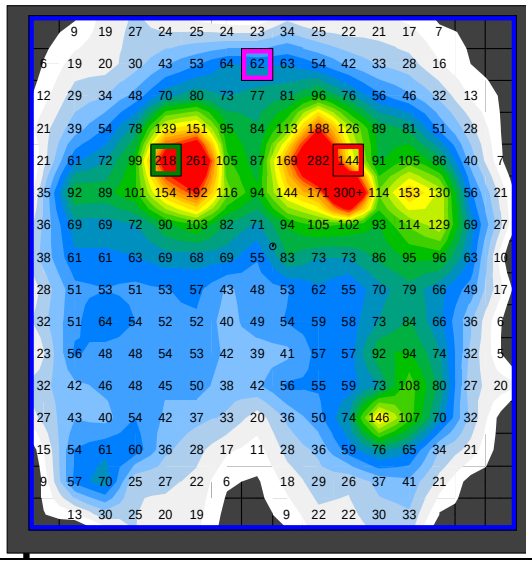
Trial 2

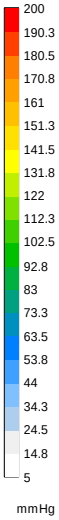


Trial 5



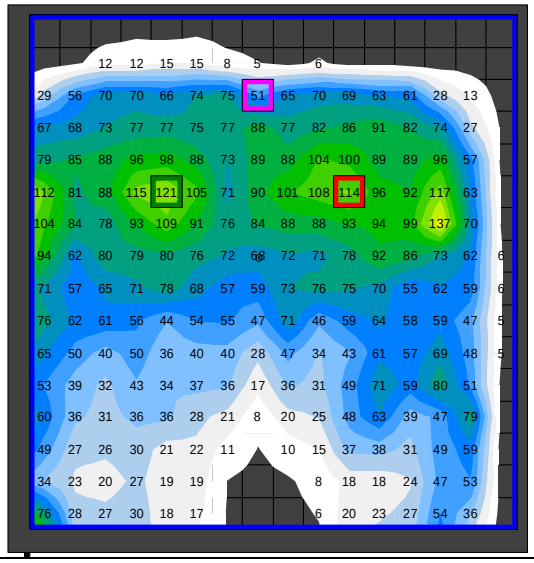
Trial 3



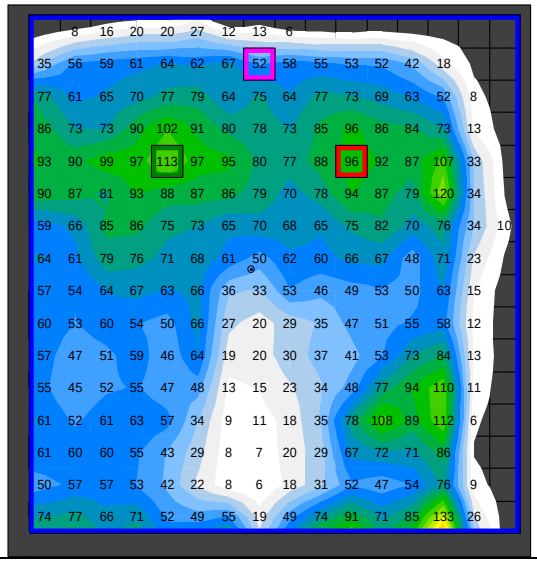


Volunteer 6, New Cushion

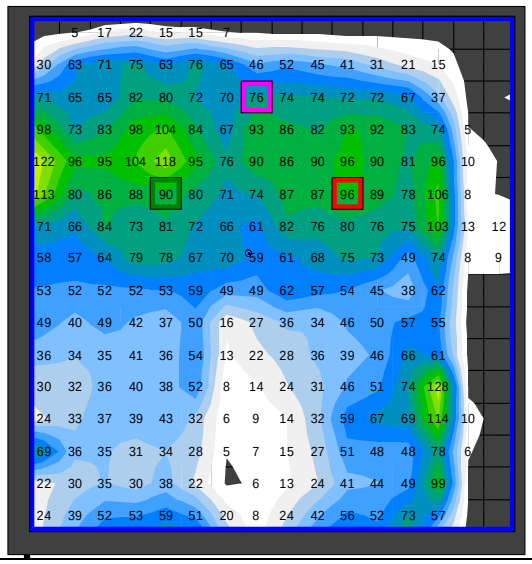
Trial 1



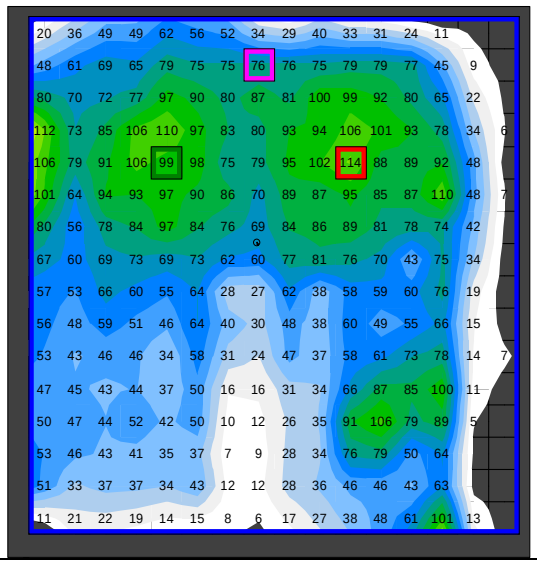
Trial 4



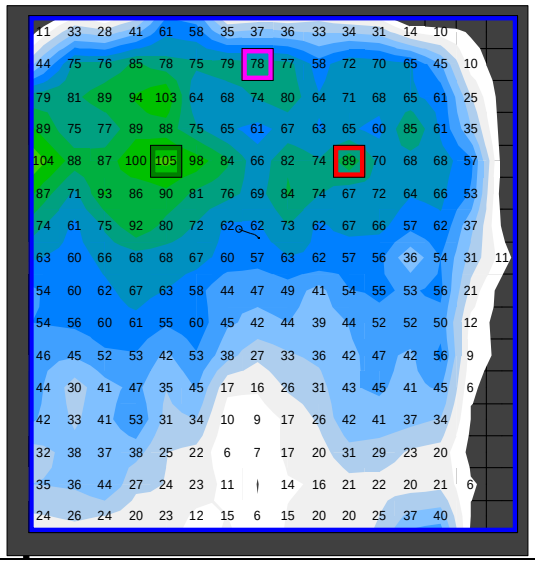
Trial 2

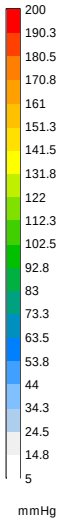


Trial 5



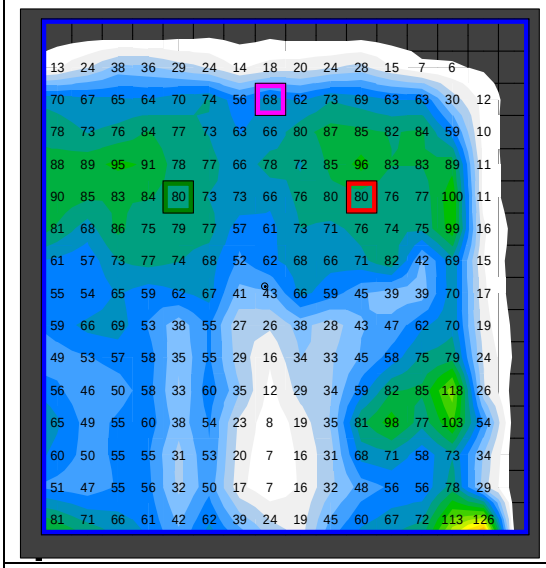
Trial 3



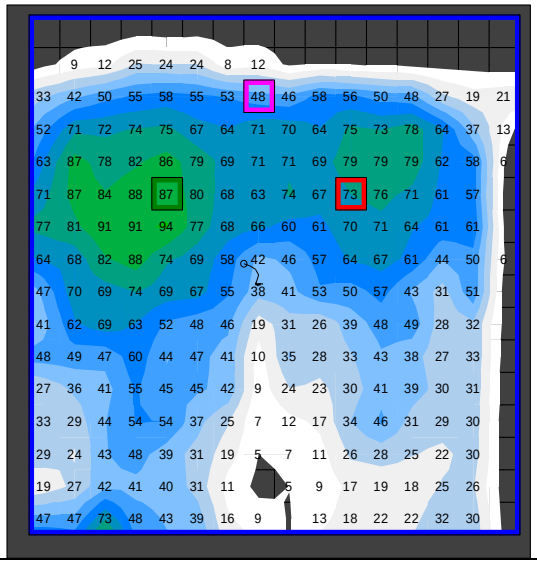


Volunteer 6, Aged Cushion

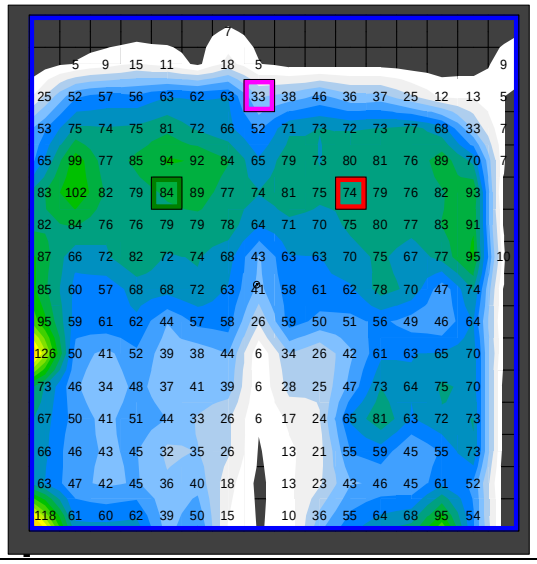
Trial 1



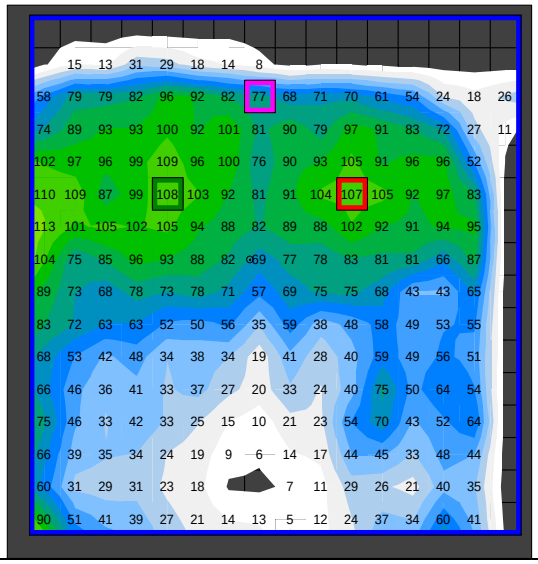
Trial 4



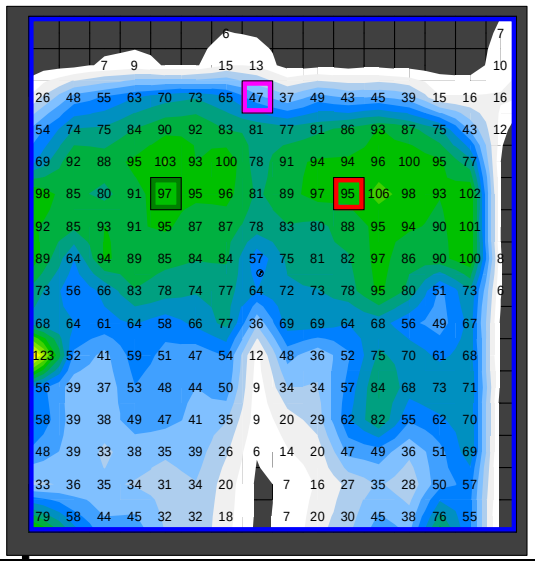
Trial 2

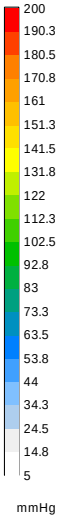


Trial 5



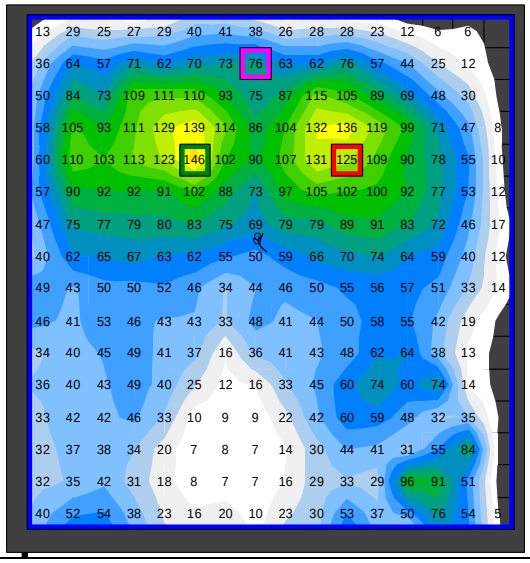
Trial 3



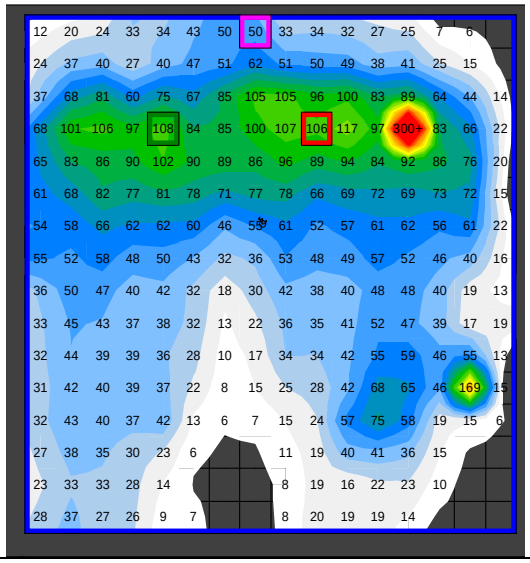


Volunteer 6, Reference Foam

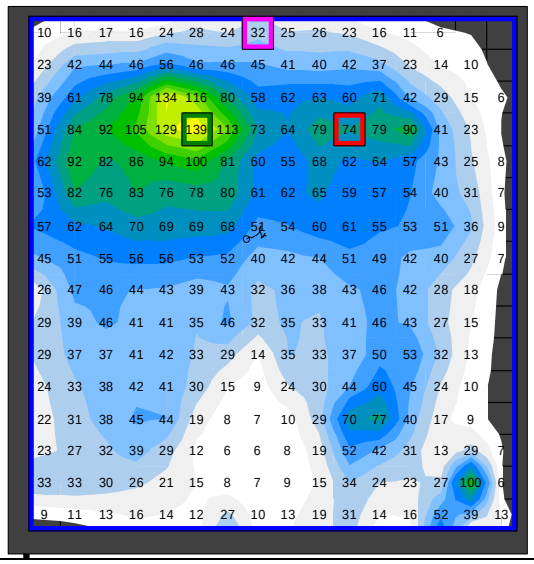
Trial 1



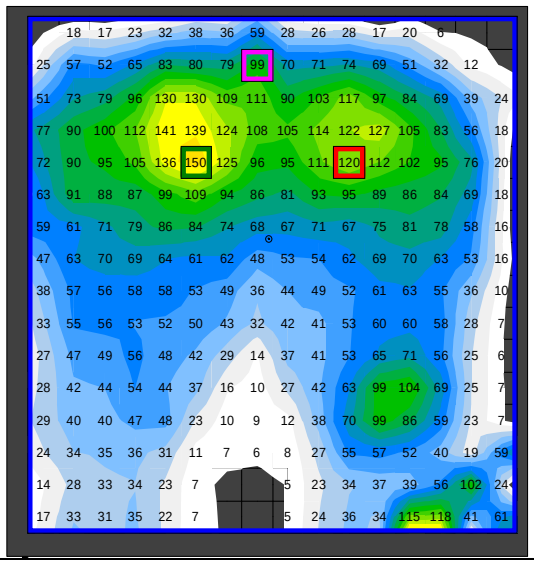
Trial 4



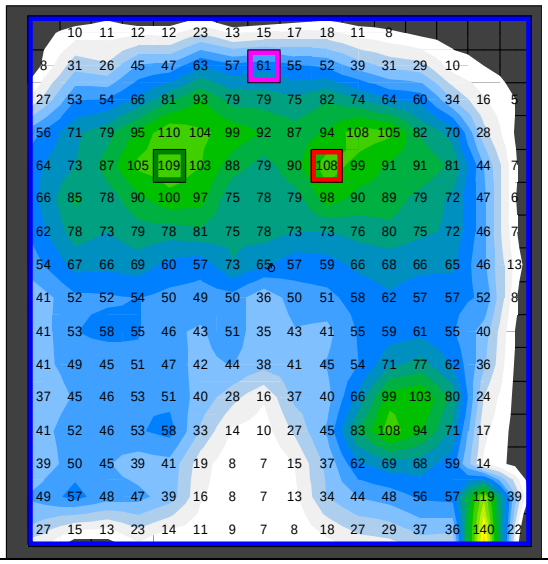
Trial 2

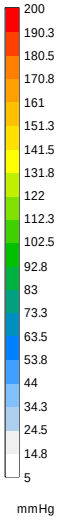


Trial 5



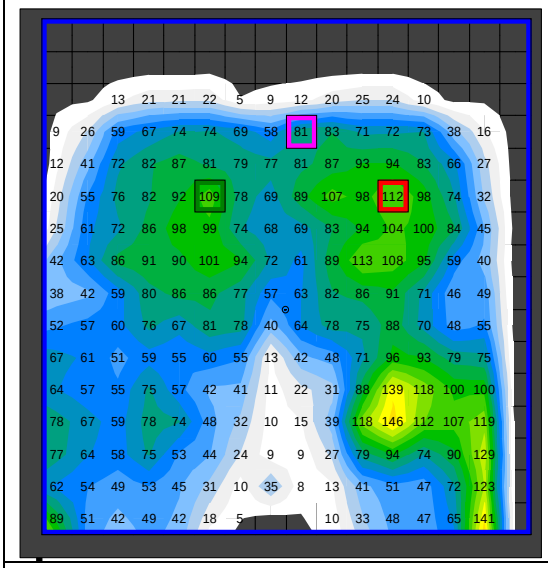
Trial 3



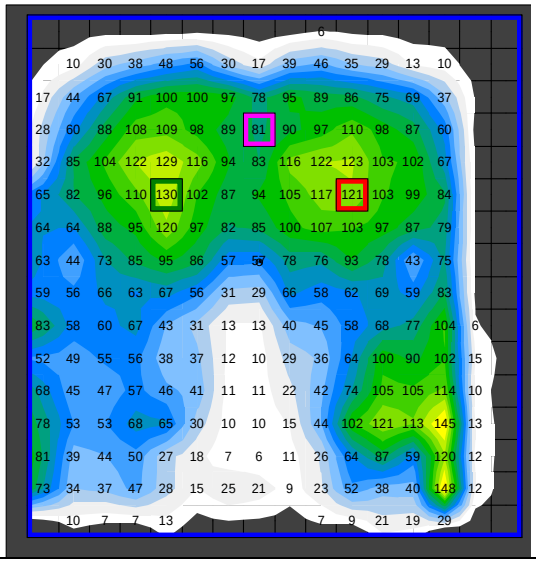


Volunteer 7, New Cushion

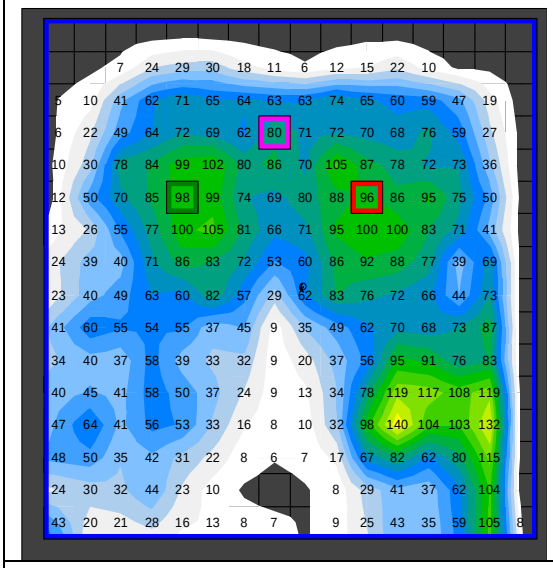
Trial 1



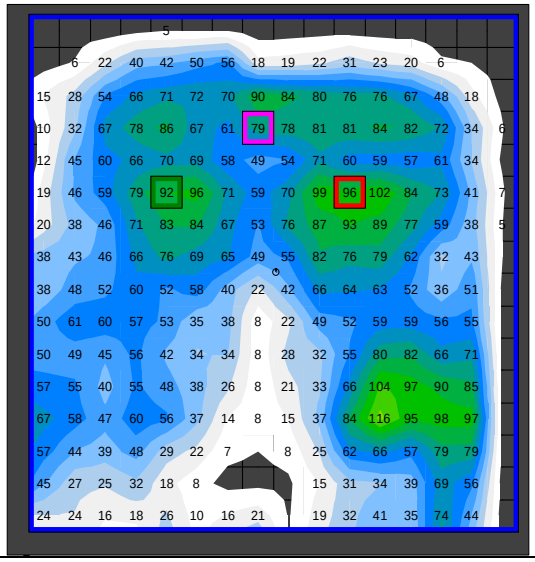
Trial 4



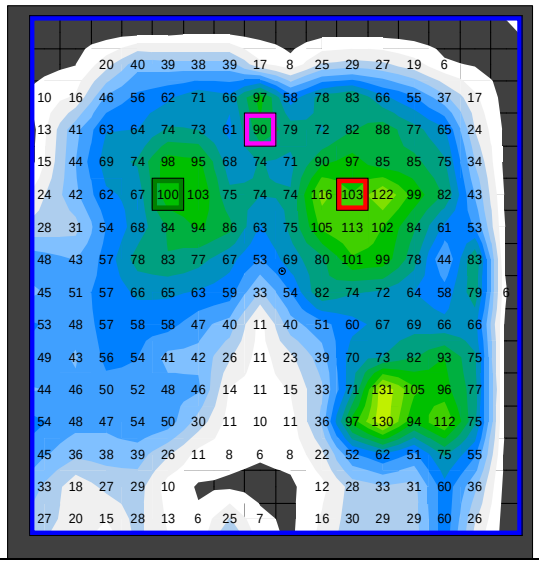
Trial 2

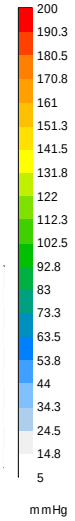


Trial 5



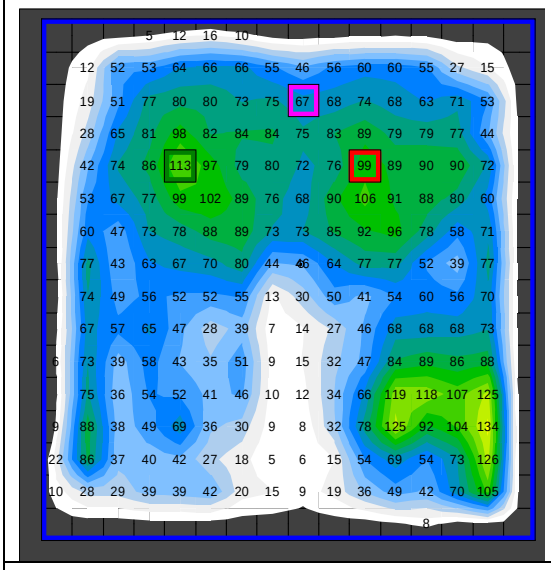
Trial 3



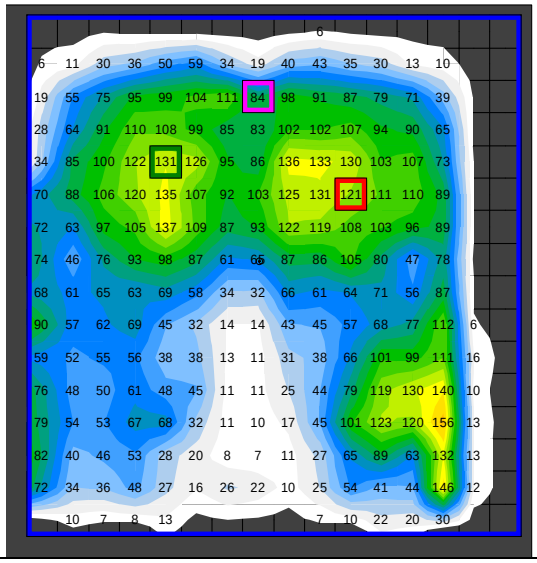


Volunteer 7, Aged Cushion

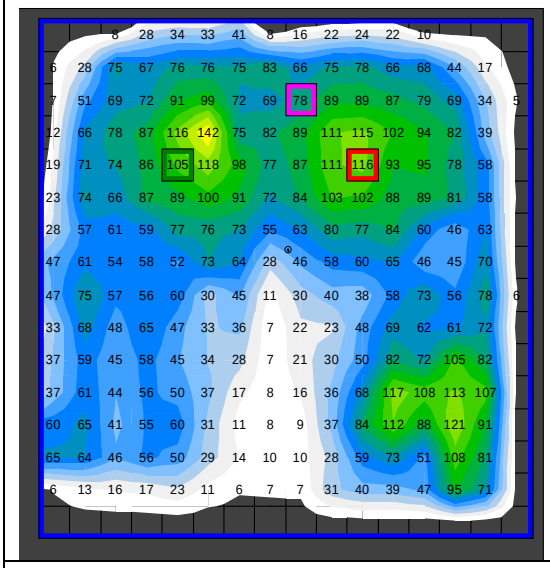
Trial 1



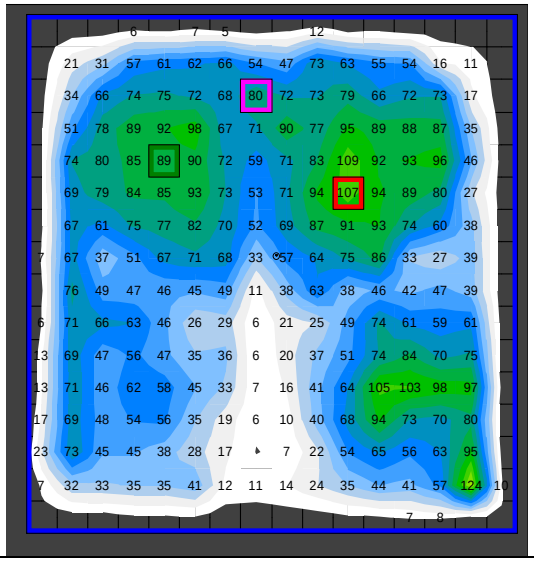
Trial 4



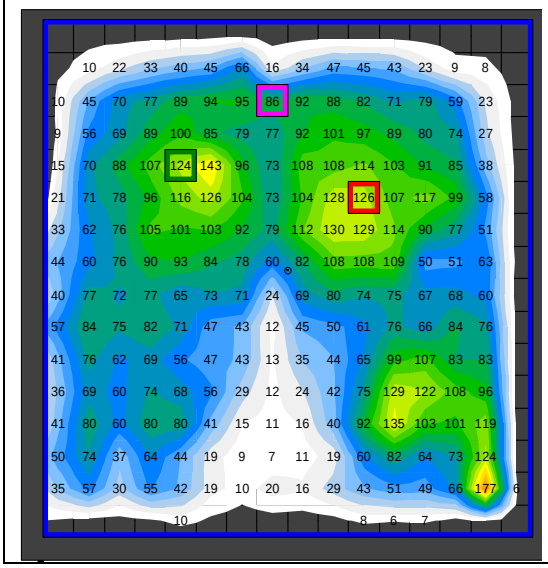
Trial 2

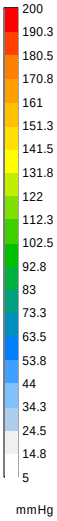


Trial 5



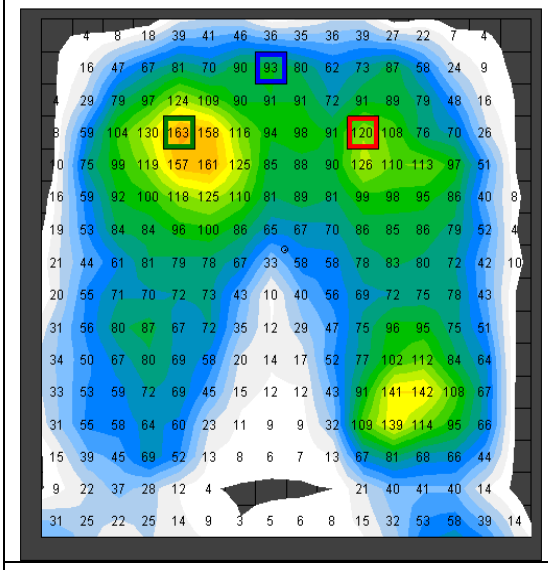
Trial 3



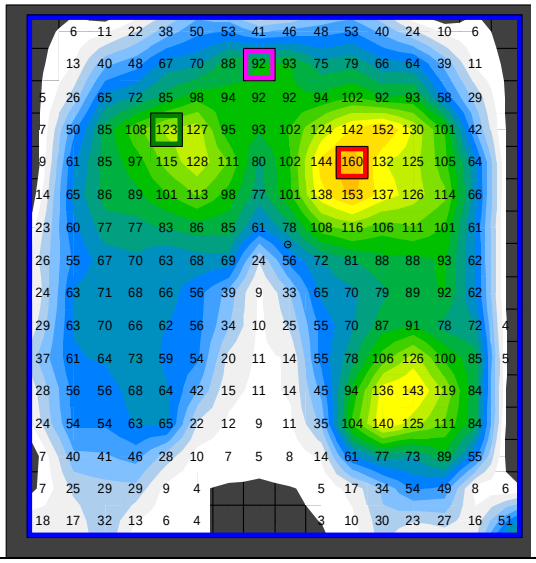


Volunteer 7, Reference Foam

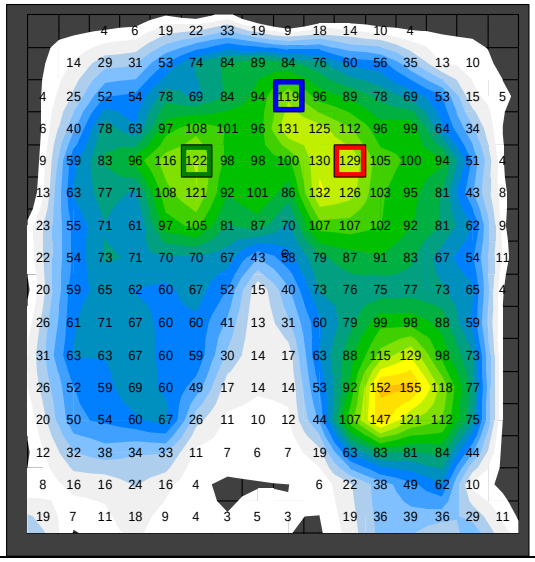
Trial 1



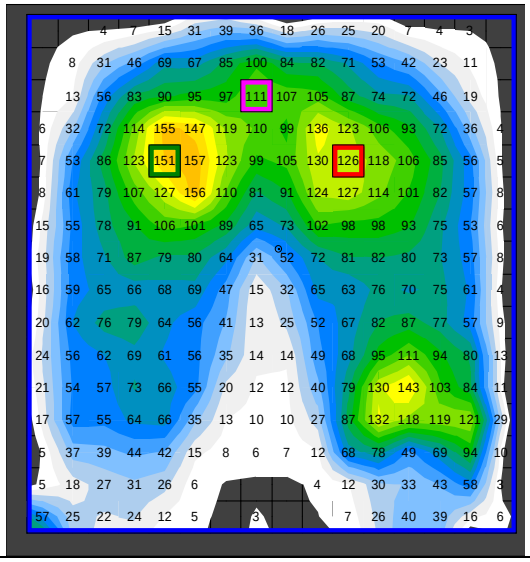
Trial 4



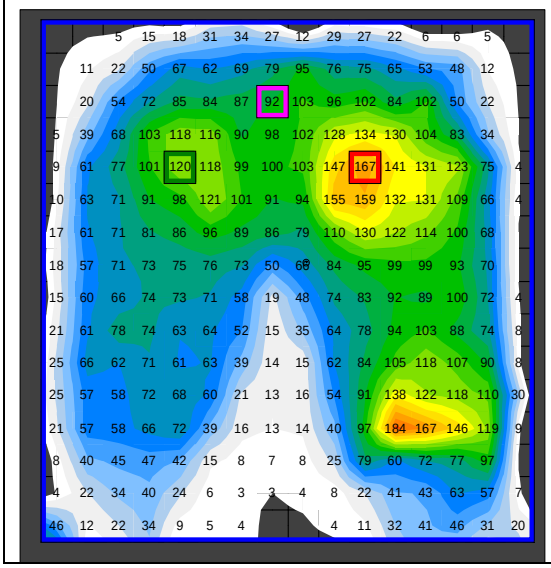
Trial 2

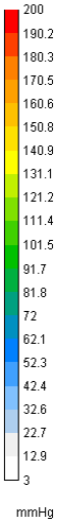


Trial 5



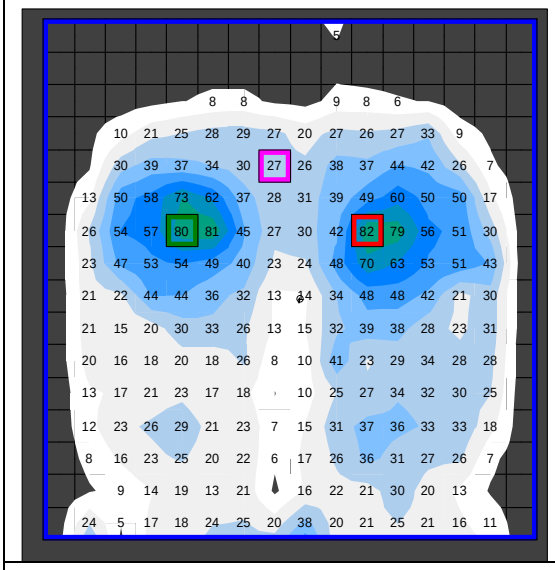
Trial 3



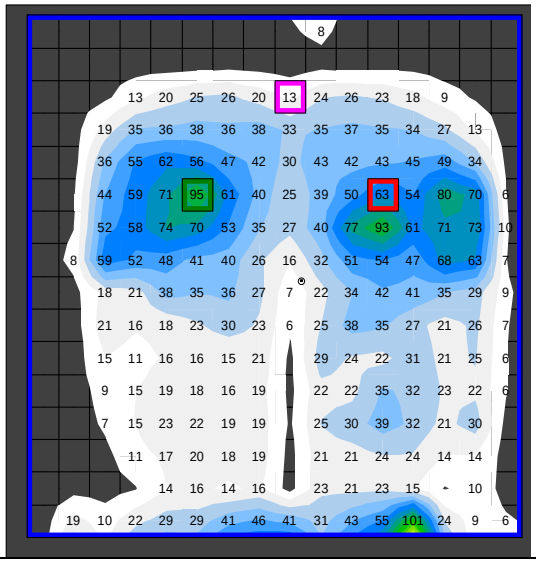


Volunteer 8, New Cushion

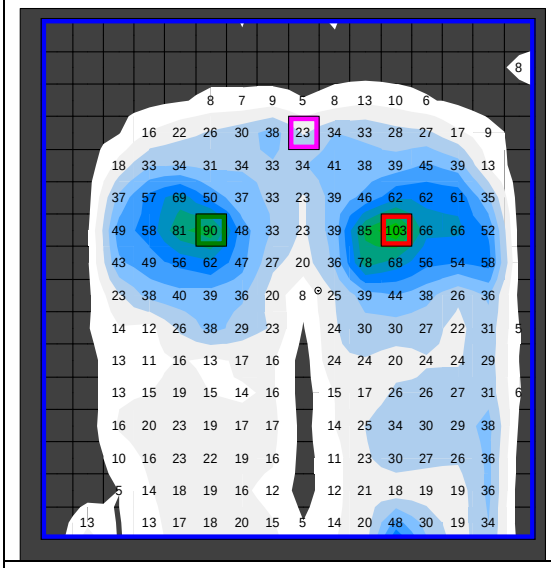
Trial 1



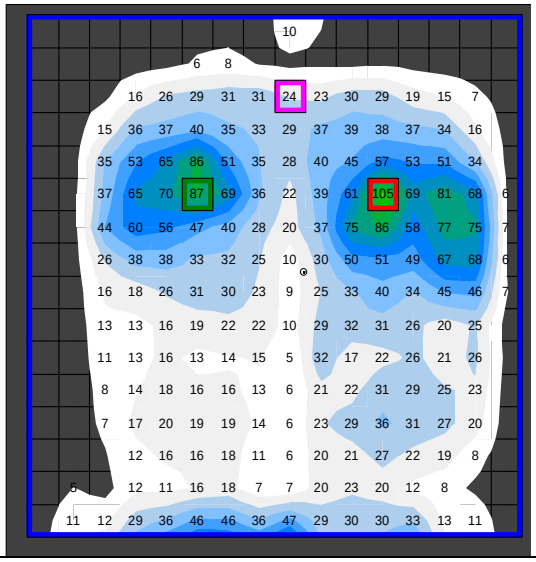
Trial 4



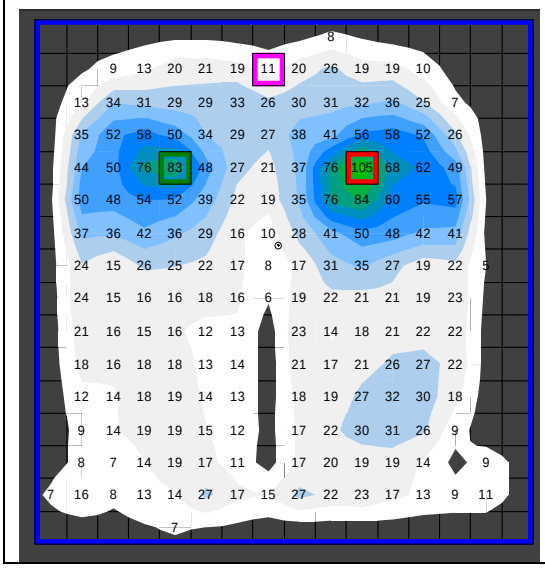
Trial 2

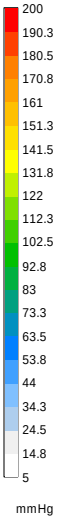


Trial 5



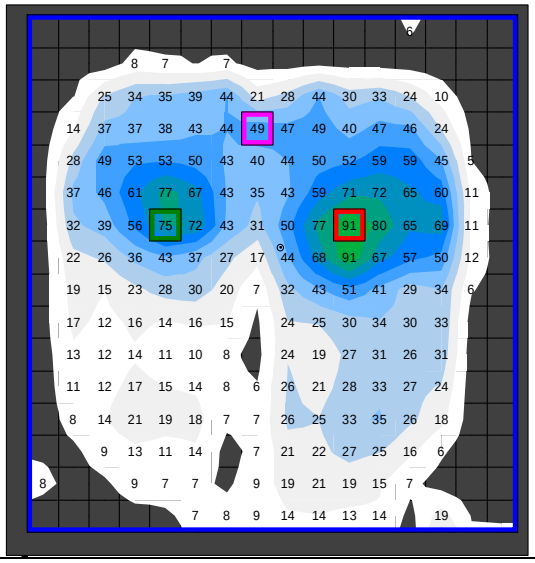
Trial 3



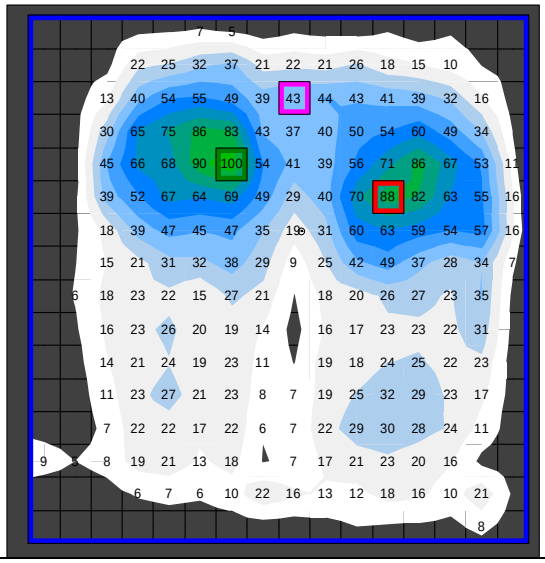


Volunteer 8, Aged Cushion

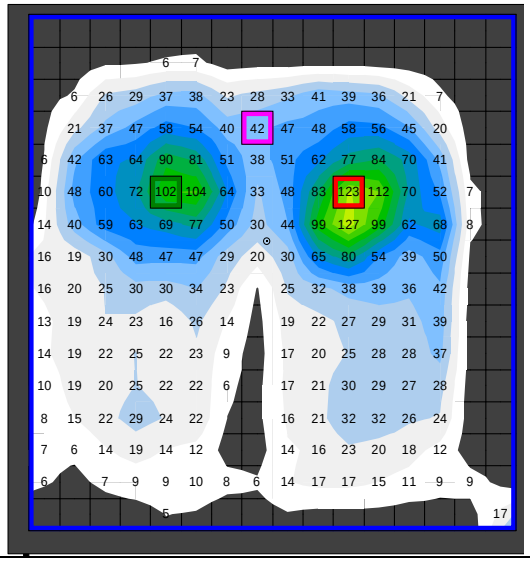
Trial 1



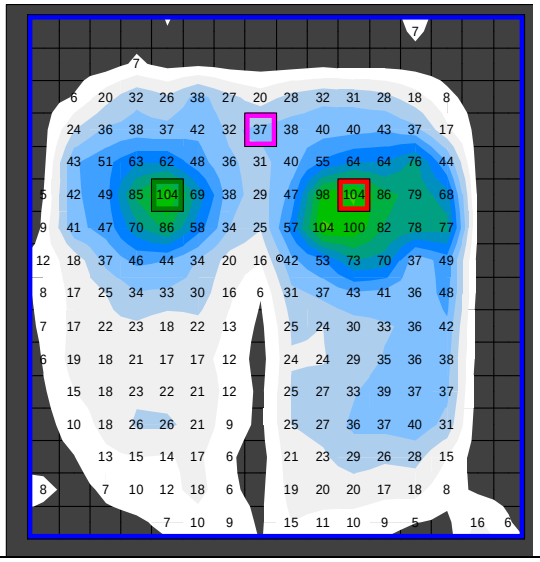
Trial 4



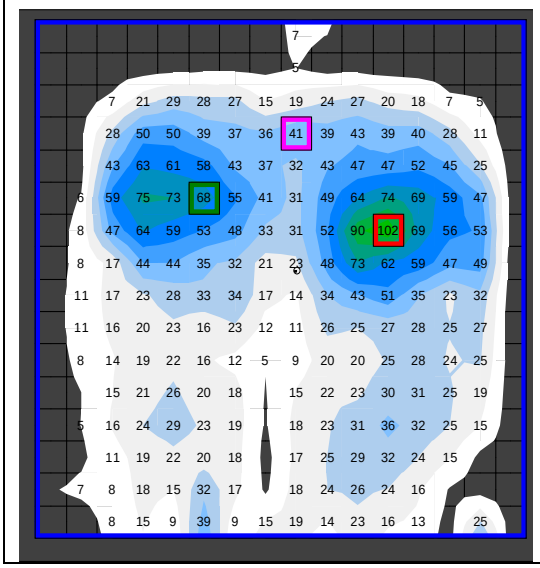
Trial 2

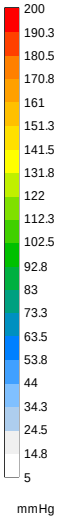


Trial 5



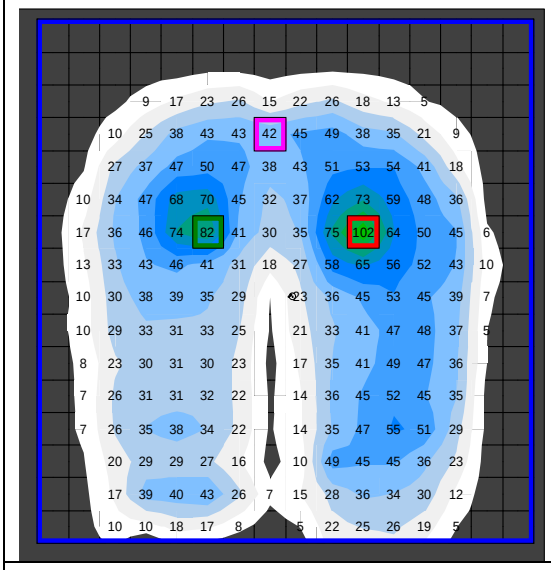
Trial 3



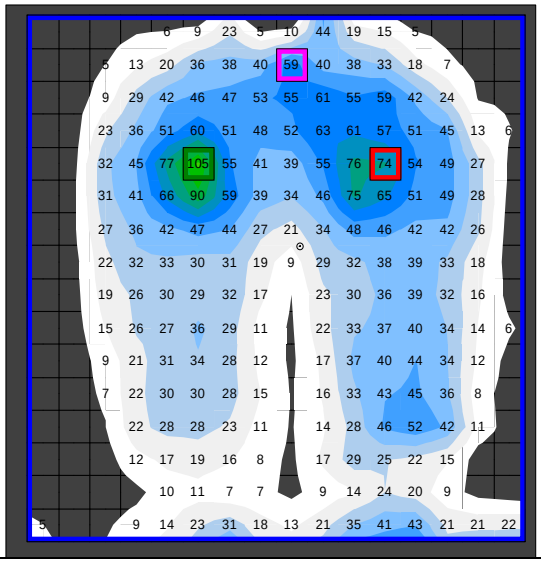


Volunteer 8, Reference Foam

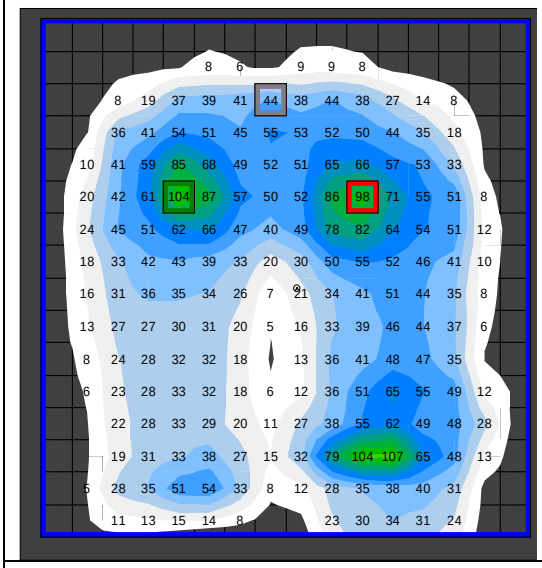
Trial 1



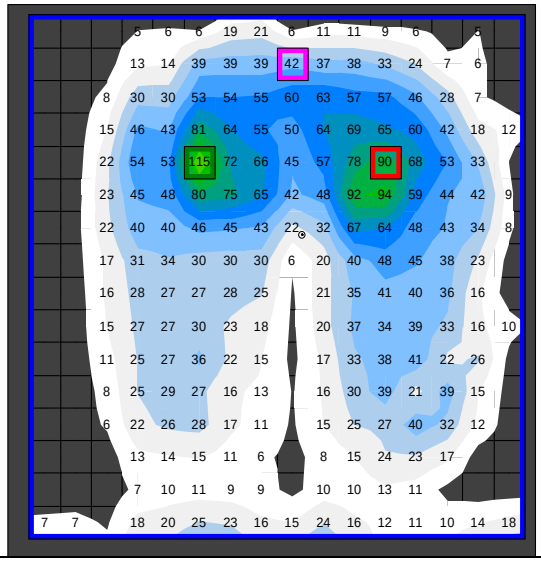
Trial 4



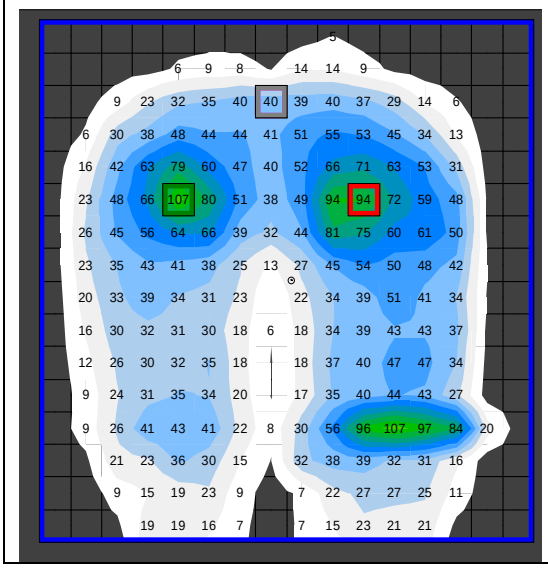
Trial 2

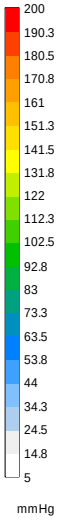


Trial 5



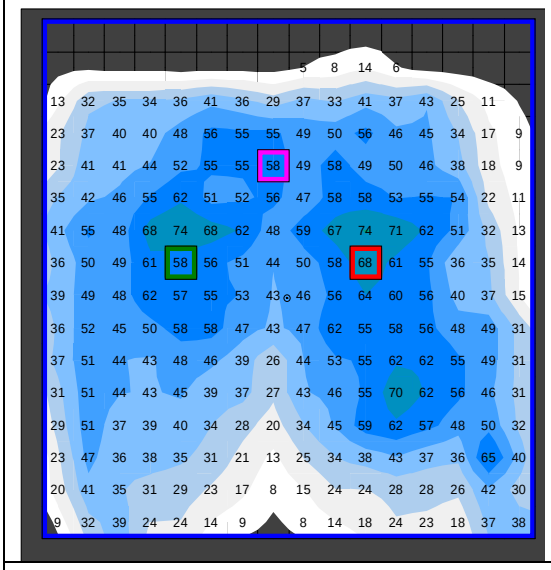
Trial 3



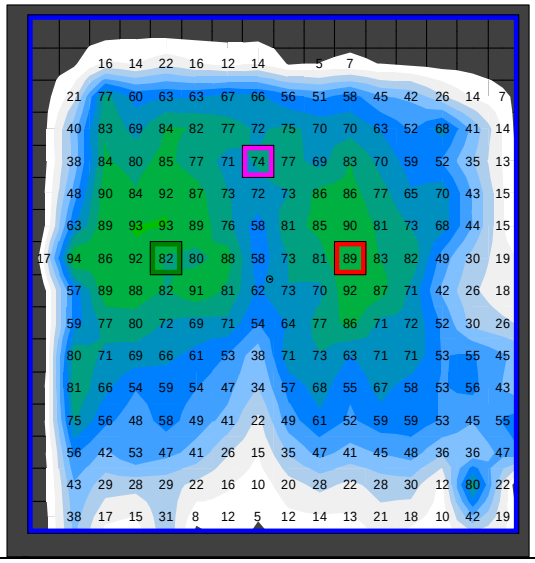


Volunteer 9, New Cushion

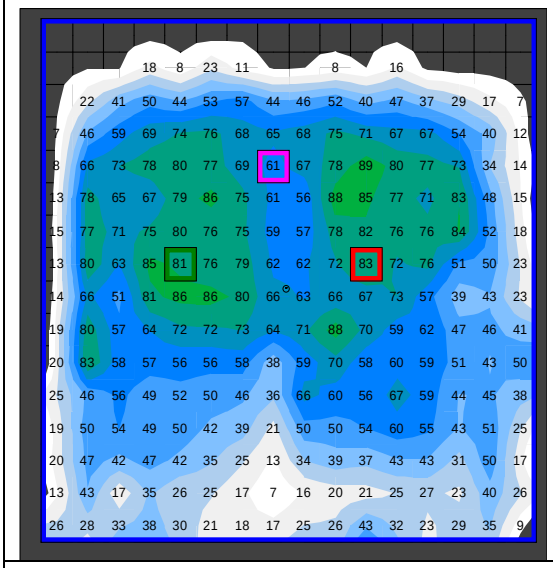
Trial 1



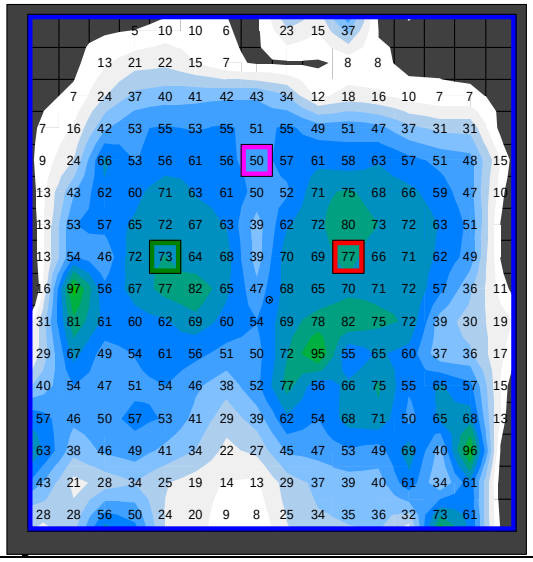
Trial 4



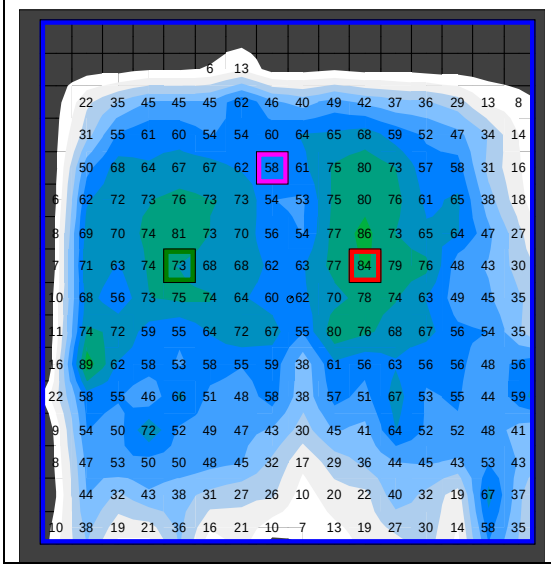
Trial 2

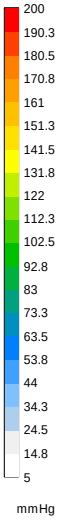


Trial 5



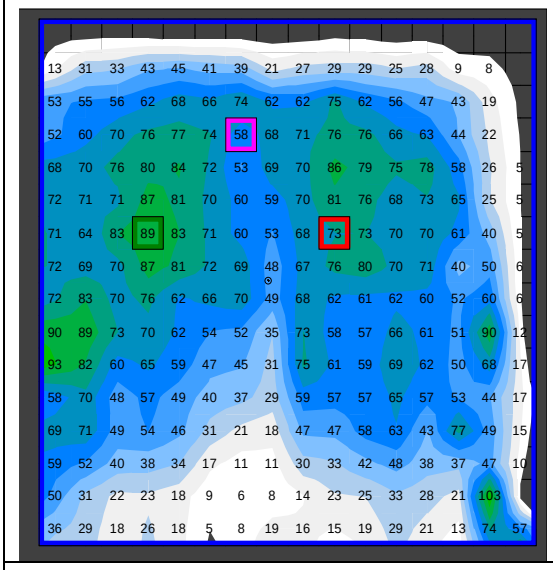
Trial 3



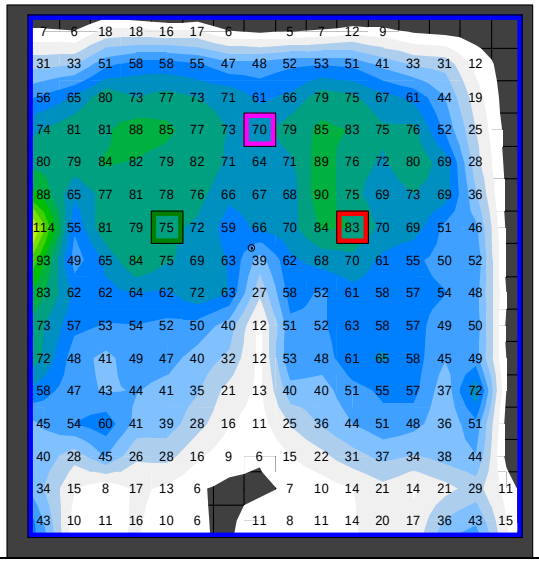


Volunteer 9, Aged Cushion

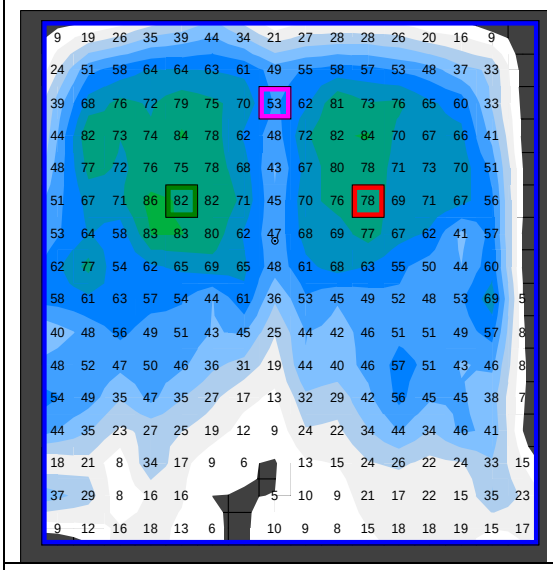
Trial 1



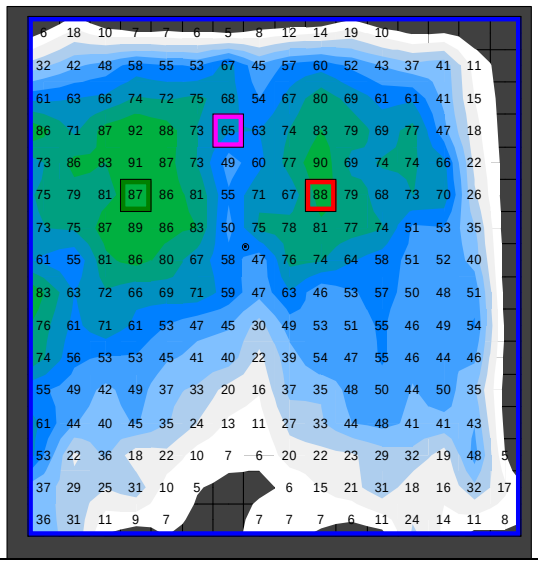
Trial 4



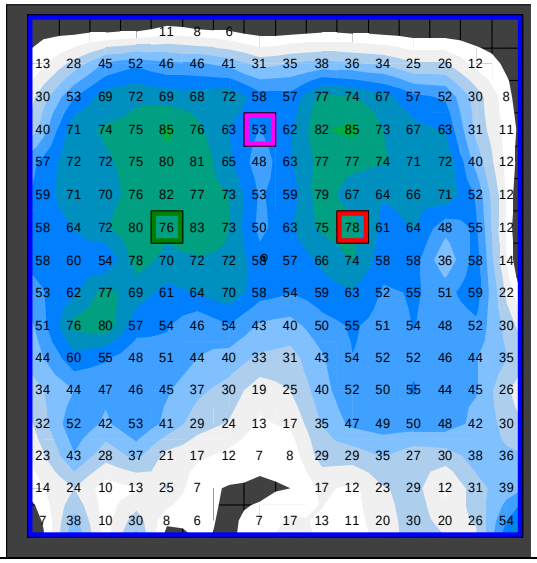
Trial 2

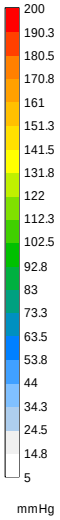


Trial 5



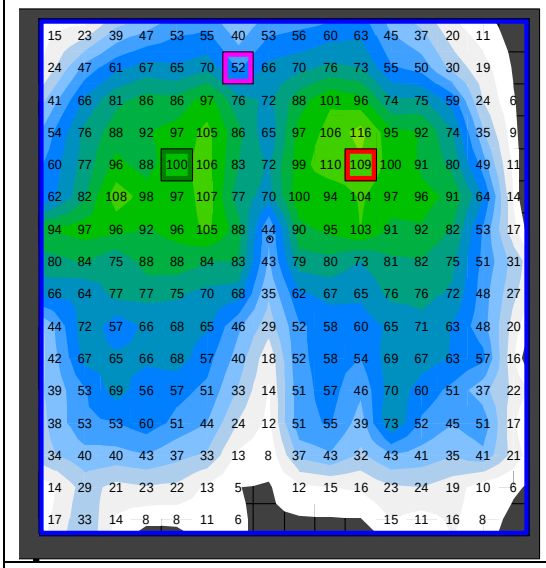
Trial 3



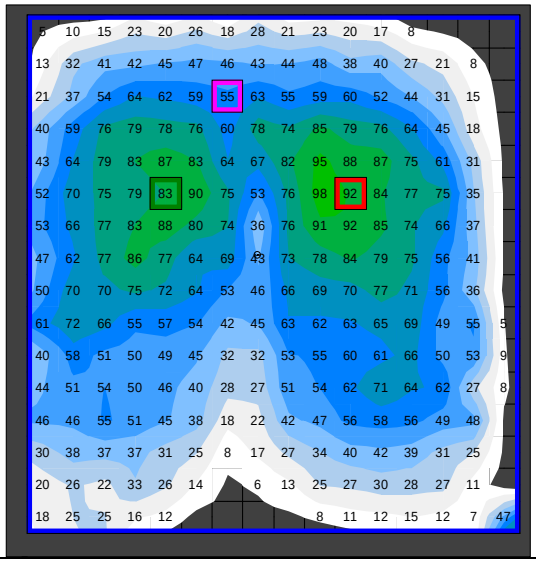


Volunteer 9, Reference Foam

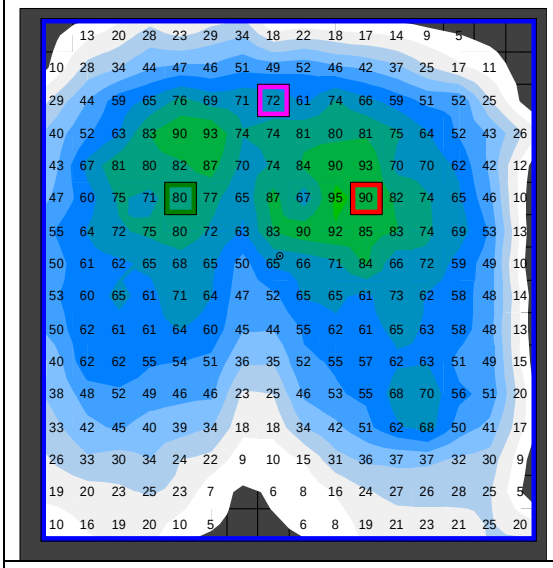
Trial 1



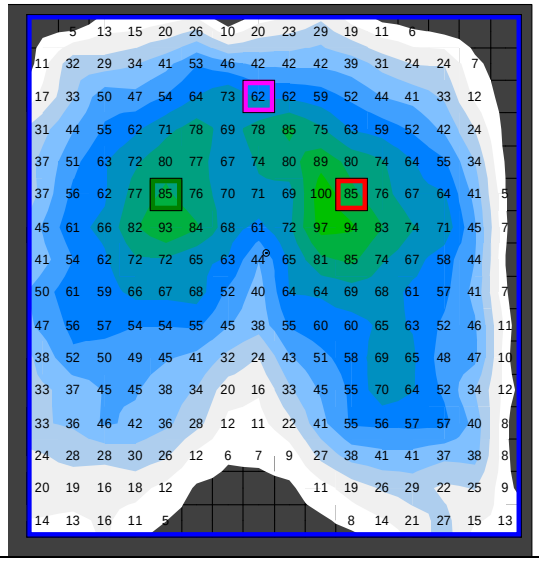
Trial 4



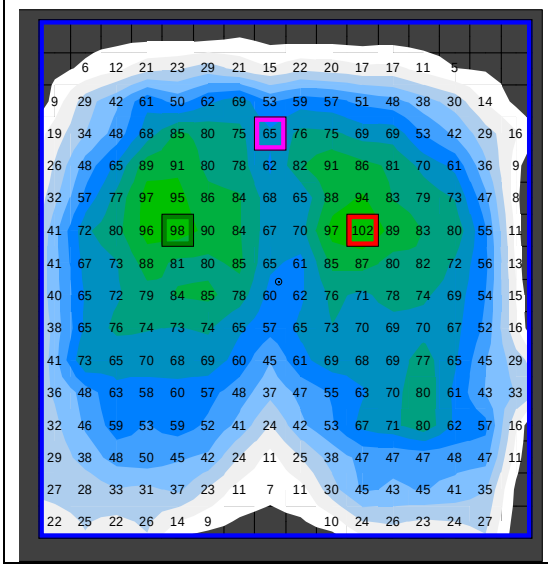
Trial 2

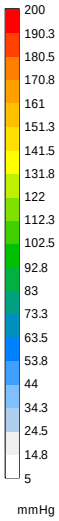


Trial 5



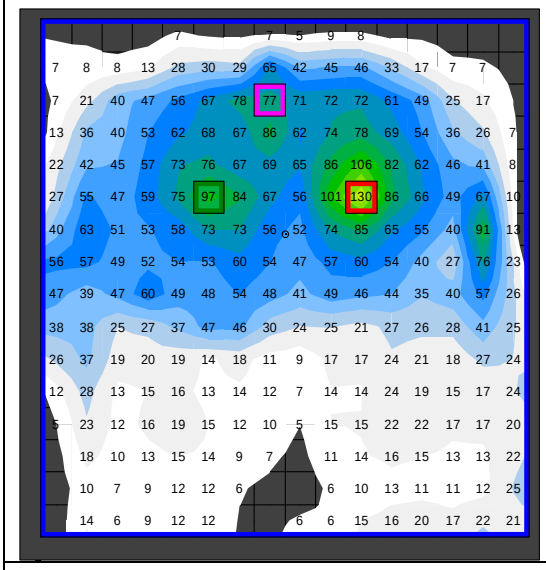
Trial 3



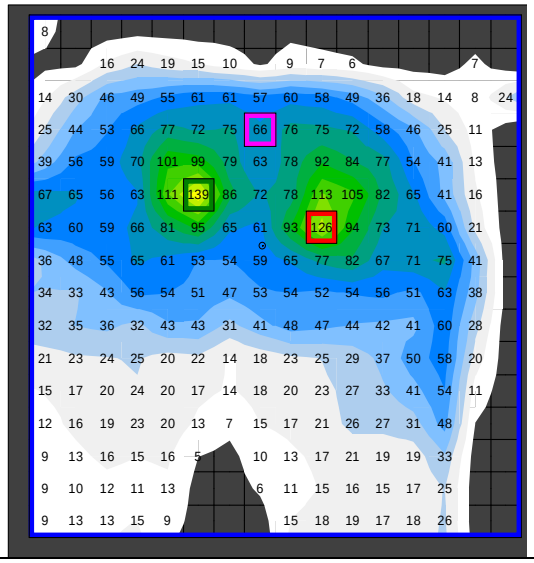


Volunteer 10, New Cushion

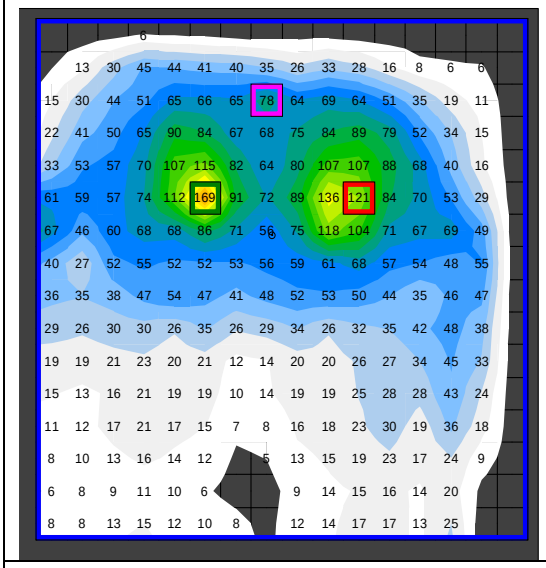
Trial 1



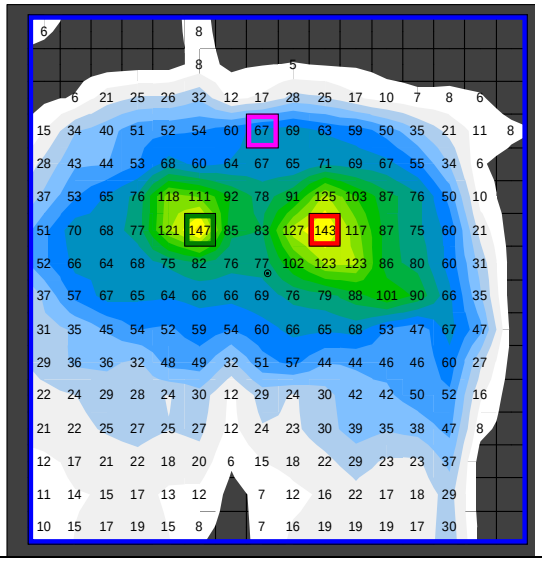
Trial 4



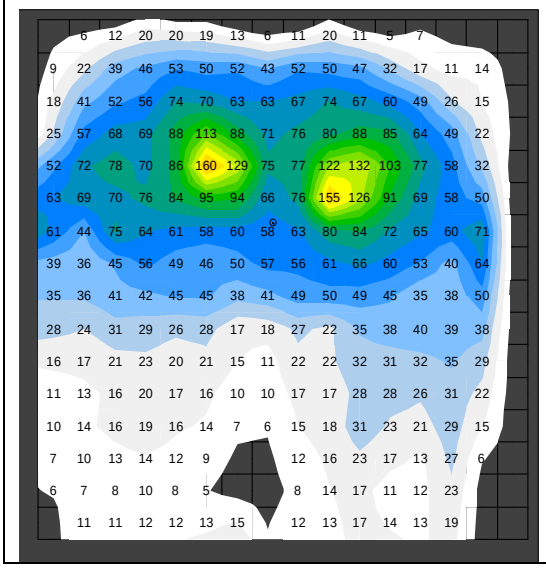
Trial 2

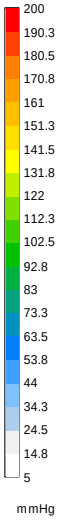


Trial 5



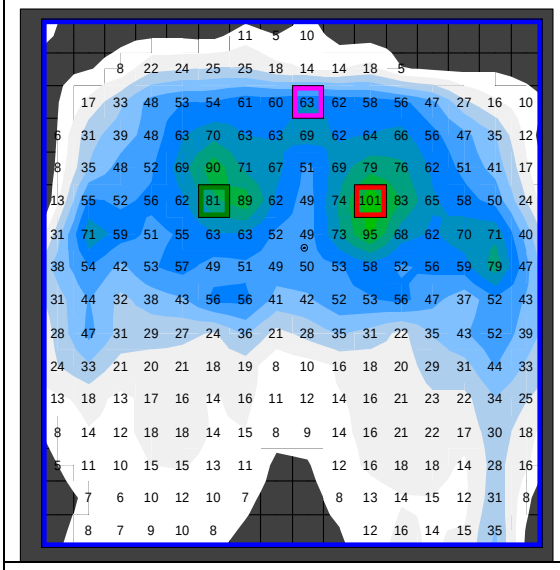
Trial 3



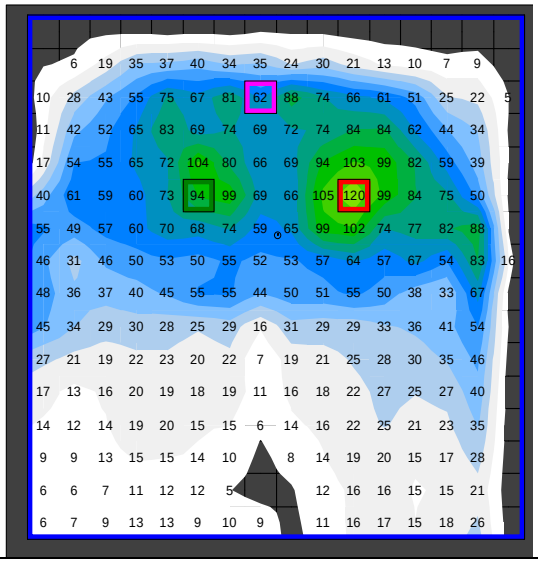


Volunteer 10, Aged Cushion

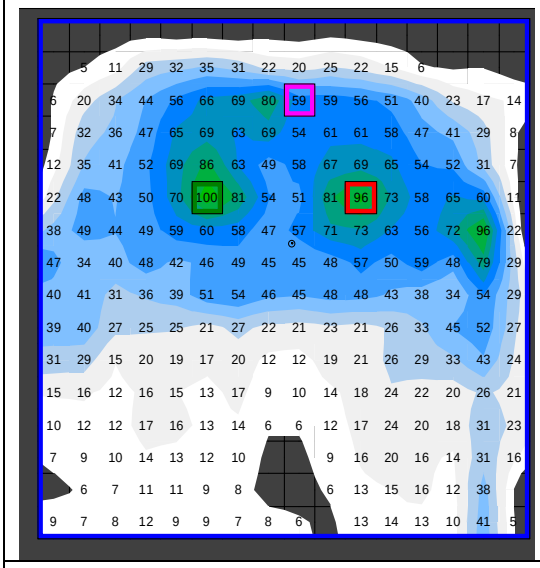
Trial 1



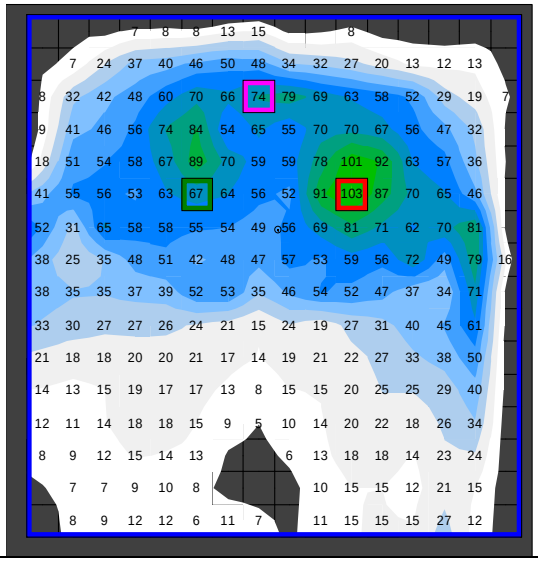
Trial 4



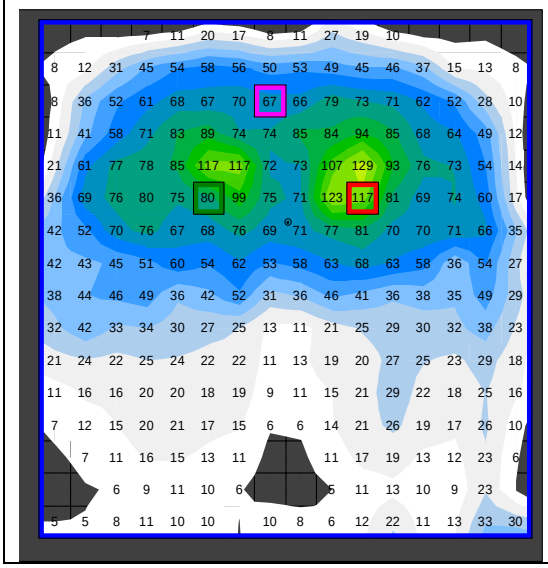
Trial 2

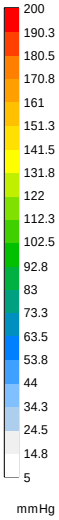


Trial 5



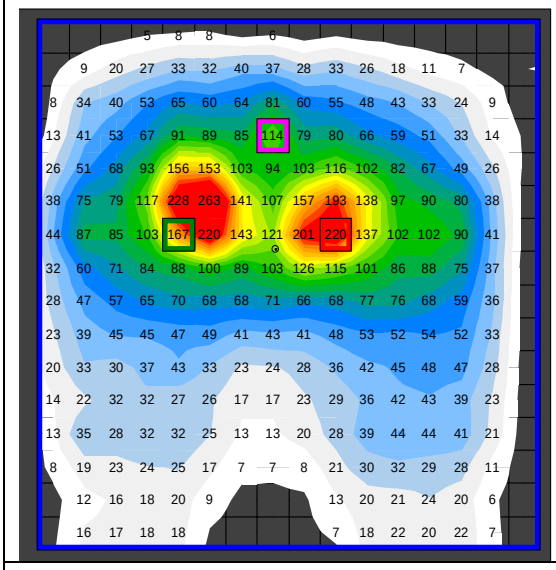
Trial 3



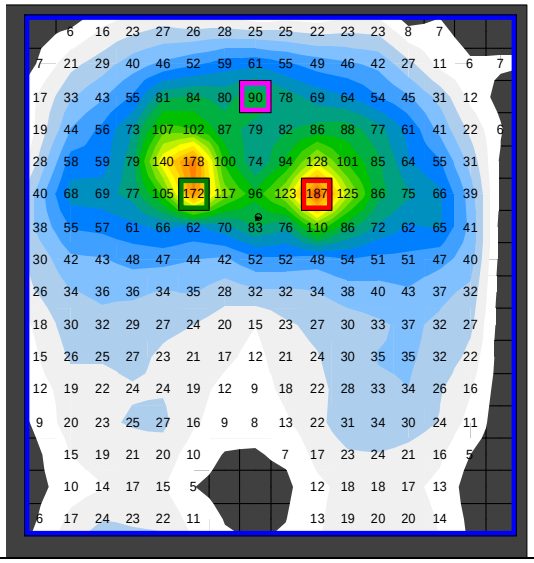


Volunteer 10, Reference Foam

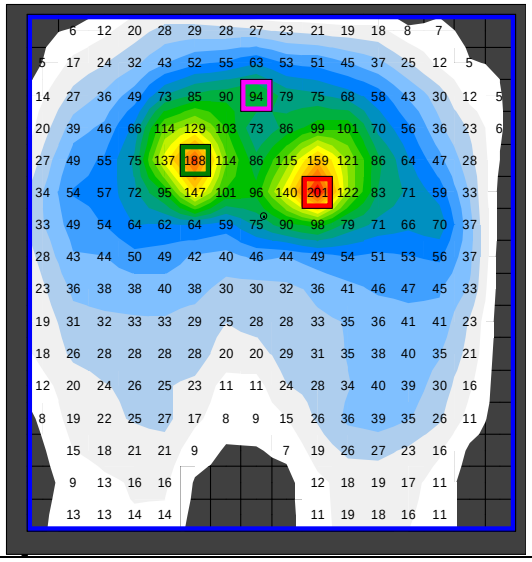
Trial 1



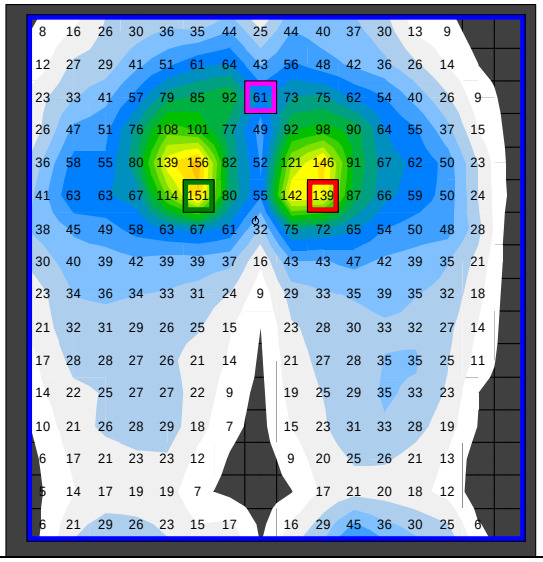
Trial 4



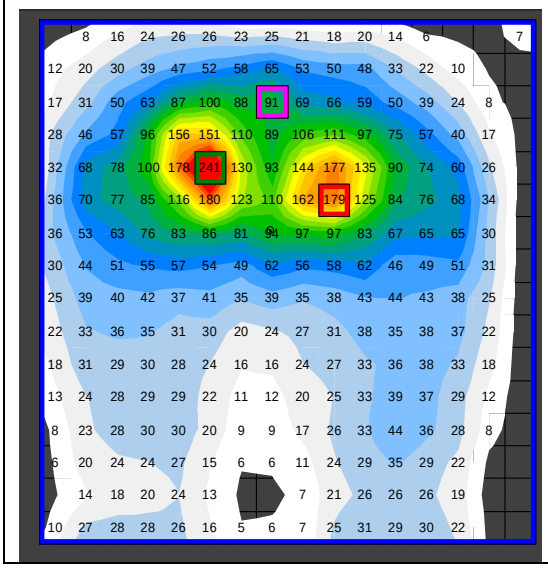
Trial 2

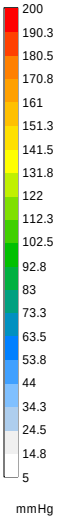


Trial 5



Trial 3





Quality Inspection		
Object	**Checked by:**	**Date**
Project number labeled	NCall	22 July 2014
Date report submitted	NCall	22 July 2014
Page numbers in footer	NCall	22 July 2014
File path in footer	NCall	22 July 2014
Customer contact information correct	NCall	22 July 2014
Table of contents displaying correct page numbers/headers	NCall	22 July 2014
Background statement depicts necessity of testing	NCall	22 July 2014
Executive summary encompasses testing conclusions	NCall	22 July 2014
References are accurate (i.e., correct protocol listed)	NCall	22 July 2014
All testing materials listed along with any ECS Receipt numbers, lot numbers, version numbers, and detailed description	NCall	22 July 2014
Method accurately describes testing performed	NCall	22 July 2014
Check all Figure/Table numbers match with reference to Figure/Table	NCall	22 July 2014
Data and analysis file path labeled	NCall	22 July 2014
Confirm Pass/Fail Values	NCall	22 July 2014
Alpha values (or percent confidence) are identified for all confidence intervals	NCall	22 July 2014
Conclusions accurately describe results from data	NCall	22 July 2014
Conclusions make sense and are clear and concise	NCall	22 July 2014
All pictures/figures in document are compressed to "print" with a resolution of 200 dpi	NCall	22 July 2014
Statement of uncertainty included with confidence interval statements	NCall	22 July 2014
Check that all comparable graphs use the same scale	NCall	22 July 2014
Check that the scale for comparable graphs is based on the highest compared value	NCall	22 July 2014
Document signed and signatures displayed on title page	NCall	22 July 2014