Bio Mat Body Temperature Test Protocol

Date of protocol: November 22, 2007

Test facility: Teletherm Infrared Systems / Research GJ Rockley Director of Operation

Consultant: Kevin Walls RAC Principal Consultant

Regulatory Insite Inc.

Address: 130 Red Fox Lane Littleton

Colorado 80127 USA

Equipment: 1. Infrared camera

2. Bio Mat Professional

A. Test Protocol – Maximum setting (158°F/70°C), 60 minutes:

- 1. Person to be imaged (subject) dresses in normal undergarments and light cotton pajamas or nightgown.
- 2. Turn on Bio Mat to maximum setting and wait 5 minutes for temperature of Bio Mat to stabilize.
- 3. Subject lies on subject's side, next to the Bio Mat, but not yet on it. Single full-length thermal image is taken of subject from top of head to bottom of feet from the back of the subject (image).
 - NOTE: Timing is important from the moment that the first image is taken, since subject's skin temperature measurements are grafted over a timescale.
- 4. Subject lies on back against mat after initial image is taken. (Time = 0 seconds)
- 5. Subject roles onto subject's side and image is taken at 30 seconds. Subject lies on back against mat immediately after image is taken.
- 6. Steps 5 and 6 are repeated at 60, 90, 120, 180, 240, 300, 600, 900, 1200, 1800, 2400, 3000 and 3600 seconds.
- 7. After image is taken at 3600 seconds, subject stands up and Bio Mat is turned off.
- 8. Full-length images are repeated at 3630, 3660, 3690 and 3720 seconds.
- 9. Grafts will be produced showing temperatures at each time interval for the center of the back of the head, upper-middle back, lower-middle back, buttocks, middle back of thigh and middle back of calf.
- 10. All images will be retained as supporting data for the final report.

GJ Rockley Director of Operation Teletherm Infrared Systems / Research

Bio Mat Skin Temperature Maximum setting (158°F/70°C) Test Data

(1) Back of Head

Maximum setting (158°F/70°C)

Time	Temperature
0 sec.	79.88°F
30 sec.	82.94°F
60 sec.	82.94°F
90 sec.	83.12°F
120 sec.	84.56°F
180 sec.	83.84°F
240 sec.	81.86°F
300 sec.	81.86°F
600 sec.	85.28°F
900 sec.	82.58°F
1200 sec.	84.92°F
1800 sec.	82.58°F
2400 sec.	82.22°F
3000 sec.	83.66°F
3600 sec.	84.20°F

(2) Upper Middle Back

Maximum setting (158°F/70°C)

Time	Temperature
0 sec.	81.14°F
30 sec.	84.20°F
60 sec.	84.20°F
90 sec.	84.92°F
120 sec.	85.82°F
180 sec.	86.00°F
240 sec.	86.18°F
300 sec.	86.00°F
600 sec.	90.14°F
900 sec.	91.58°F
1200 sec.	94.46°F
1800 sec.	94.28°F
2400 sec.	93.74°F
3000 sec.	95.00°F
3600 sec.	94.82°F

Time	Temperature
3630 sec.	94.28°F
3660 sec.	93.38°F
3690 sec.	92.66°F
3720 sec.	91.40°F

(3) Lower Middle Back

Maximum setting (158°F/70°C)

Time	Temperature
0 sec.	83.12°F
30 sec.	84.56°F
60 sec.	84.56°F
90 sec.	85.64°F
120 sec.	86.18°F
180 sec.	86.56°F
240 sec.	86.36°F
300 sec.	86.72°F
600 sec.	90.68°F
900 sec.	93.20°F
1200 sec.	95.36°F
1800 sec.	95.18°F
2400 sec.	97.52°F
3000 sec.	96.98°F
3600 sec.	97.52°F

(4) Buttocks

Maximum setting (158°F/70°C)

Time	Temperature
	-
0 sec.	79.52°F
30 sec.	82.40°F
60 sec.	84.02°F
90 sec.	83.66°F
120 sec.	82.22°F
180 sec.	83.12°F
240 sec.	82.22°F
300 sec.	83.30°F
600 sec.	88.88°F
900 sec.	88.88°F
1200 sec.	92.30°F
1800 sec.	94.10°F
2400 sec.	85.82°F
3000 sec.	91.22°F
3600 sec.	93.74°F

After Turn off the Biomat

Time	Temperature
3630 sec.	91.58°F
3660 sec.	92.30°F
3690 sec.	93.20°F
3720 sec.	93.02°F

Time	Temperature
3630 sec.	86.90°F
3660 sec.	85.46°F
3690 sec.	87.44°F
3720 sec.	87.62°F

(5) Lower Middle Back

Maximum setting (158°F/70°C)

Time	Temperature
0 sec.	83.84°F
30 sec.	87.08°F
60 sec.	88.88°F
90 sec.	90.32°F
120 sec.	91.22°F
180 sec.	91.76°F
240 sec.	91.22°F
300 sec.	92.84°F
600 sec.	95.36°F
900 sec.	95.18°F
1200 sec.	95.18°F
1800 sec.	95.72°F
2400 sec.	94.28°F
3000 sec.	96.62°F
3600 sec.	95.18°F

(6) Buttocks

Maximum setting (158°F/70°C)

Time	Temperature
0 sec.	83.84°F
30 sec.	87.98°F
60 sec.	90.14°F
90 sec.	91.40°F
120 sec.	90.68°F
180 sec.	91.22°F
240 sec.	91.58°F
300 sec.	92.66°F
600 sec.	95.54°F
900 sec.	96.08°F
1200 sec.	96.80°F
1800 sec.	96.72°F
2400 sec.	95.36°F
3000 sec.	96.44°F
3600 sec.	95.72°F

After Turn off the Biomat

Time	Temperature
3630 sec.	92.48°F
3660 sec.	92.30°F
3690 sec.	91.94°F
3720 sec.	92.12°F

Time	Temperature
3630 sec.	91.40°F
3660 sec.	89.78°F
3690 sec.	85.46°F
3720 sec.	85.64°F

B. Test Protocol – Low setting (113°F /45°C), 8 hours:

- 1. Person to be imaged (subject) dresses in normal undergarments and light cotton pajamas or nightgown.
- 2. Turn on Bio Mat to low setting (113°F/45°C) and wait 5 minutes for temperature of Bio Mat to stabilize.
- 3. Subject lies on subject's side, next to the Bio Mat, but not yet on it. Single full-length thermal image is taken of subject from top of head to bottom of feet from the back of the subject (image).
 - NOTE: Timing is important from the moment that the first image is taken, since subject's skin temperature measurements are grafted over a timescale.
- 4. Subject lies on back against mat after initial image is taken. (Time = 0 seconds)
- 5. Subject roles onto subject's side and image are taken at 30 seconds.
- 6. Subject lies on back against mat immediately after image is taken.
- 7. Steps 5 and 6 are repeated at 60, 90, 120, 180, 240, 300, 600, 900, 1800 seconds, 1 hr, 2 hr, 4 hr, 6 hr and 8 hr.
- 8. After image is taken at 3600 seconds, subject stands up and Bio Mat is turned off.
- Grafts will be produced showing temperatures at each time interval for the center of the back of the head, upper-middle back, lower-middle back, buttocks, middle back of thigh and middle back of calf.
- 10. All images will be retained as supporting data for the final report.

Bio Mat Skin Temperature Low setting (113°F/45°C) Test Data

(1) Back of Head

Low setting (113°F/45°C)

Time	Temperature
0 sec.	75.92°F
30 sec.	79.88°F
60 sec.	76.10°F
90 sec.	79.88°F
120 sec.	78.08°F
180 sec.	80.60°F
240 sec.	78.44°F
300 sec.	80.96°F
600 sec.	81.32°F
900 sec.	79.52°F
1800 sec.	83.12°F
1 hr.	81.68°F

(2) Upper Middle Back

Low setting (113°F/45°C)

Time	Temperature
0 sec.	80.60°F
30 sec.	82.40°F
60 sec.	82.76°F
90 sec.	84.02°F
120 sec.	83.12°F
180 sec.	83.84°F
240 sec.	82.04°F
300 sec.	83.48°F
600 sec.	87.62°F
900 sec.	92.84°F
1800 sec.	93.20°F
1 hr.	°F

After Turn off the Biomat

Time	Temperature
2 hr.	78.98°F
4 hr.	80.06°F
6 hr.	82.22°F
8 hr.	81.14°F

Time	Temperature
2 hr.	93.02°F
4 hr.	92.84°F
6 hr.	94.10°F
8 hr.	94.46°F

(3) Lower Middle Back

Low setting (113°F/45°C)

Time	Temperature
0 sec.	83.12°F
30 sec.	83.84°F
60 sec.	83.30°F
90 sec.	83.66°F
120 sec.	83.66°F
180 sec.	84.02°F
240 sec.	83.66°F
300 sec.	84.38°F
600 sec.	86.90°F
900 sec.	89.78°F
1800 sec.	93.74°F
1 hr.	95.36°F

(4) Buttocks

Low setting (113°F/45°C)

Time	Temperature
0 sec.	76.10°F
30 sec.	79.70°F
60 sec.	79.70°F
90 sec.	82.22°F
120 sec.	80.60°F
180 sec.	80.78°F
240 sec.	81.14°F
300 sec.	81.86°F
600 sec.	85.10°F
900 sec.	87.44°F
1800 sec.	91.04°F
1 hr.	90.68°F

After Turn off the Biomat

Time	Temperature
2 hr.	93.92°F
4 hr.	94.64°F
6 hr.	95.54°F
8 hr.	96.98°F

Time	Temperature
2 hr.	89.60°F
4 hr.	89.60°F
6 hr.	91.76°F
8 hr.	93.38°F

(5) Middle Back of Thigh

Low setting (113°F/45°C)

Time	Temperature
0 sec.	81.86°F
30 sec.	86.36°F
60 sec.	85.64°F
90 sec.	87.26°F
120 sec.	86.18°F
180 sec.	86.36°F
240 sec.	86.18°F
300 sec.	86.36°F
600 sec.	89.96°F
900 sec.	89.78°F
1800 sec.	93.38°F
1 hr.	94.10°F

(6) Middle Back of Calf

Low setting (113°F/45°C)

Time	Temperature
0 sec.	81.14°F
30 sec.	87.07°F
60 sec.	84.56°F
90 sec.	87.08°F
120 sec.	85.46°F
180 sec.	85.10°F
240 sec.	84.92°F
300 sec.	87.26°F
600 sec.	90.50°F
900 sec.	90.68°F
1800 sec.	93.74°F
1 hr.	93.56°F

After Turn off the Biomat

Time	Temperature
2 hr.	92.48°F
4 hr.	93.93°F
6 hr.	96.26°F
8 hr.	95.54°F

Time	Temperature
2 hr.	93.02°F
4 hr.	93.20°F
6 hr.	94.64°F
8 hr.	94.82°F