1. Purpose

The suite of tests outlined in this document verify that the *ActivFlow Sport* provides adequate adhesive strength during wear and minimal pain during removal to ensure the safety and comfort of the user.

1.1. Test 1 is designed to ensure that the *ActivFlow Sport's* adhesive strips are strong enough to sustain shear force resulting from impact without significant displacement on the dry skin to which it is attached. Any displacement of the device resulting from the failure of the adhesive could cause intense discomfort or injury to the user.

1.2. The purpose of Test 2 is to ensure that the *ActivFlow Sport's* adhesive strips are strong enough to sustain shear force resulting from an impact without significant displacement on the sweaty skin to which it is attached. Any displacement of the device resulting from the failure of the adhesive could cause intense discomfort or injury to the user.

1.3. Test 3 is performed to ensure that the *ActivFlow Sport's* adhesive strips can be removed from the user without causing significant pain or discomfort.

2. Scope

2.1. Test 1 will validate that the *ActivFlow Sport's* adhesive strips comply with PPR7.4, which states:

> *The adhesive that secures the band to the body shall be able to withstand 10 Newtons of shear force.*

2.2. Test 2 will validate that the *ActivFlow Sport's* adhesive strips comply with PPR7.4.1, which states:

> *The adhesive that secures the band to the body shall be able to withstand 10 Newtons of shear force when the skin is moisturized or sweaty.*

2.3. Test 3 will validate that the *ActivFlow Sport's* adhesive strips comply with PPR7.5.1, which states:

> *ActivFlow Sport's adhesive patches shall be removed with no more than moderate pain (3-4 on 10 point pain scale).*

3. Reference Documents

3.1. *ActivFlow Sport* PRD

3.2. *ActivFlow Sport* Risk Assessment

4. Experimental Tools and Materials

4.1. Tests 1 & 2:

4.1.1. Instron 5900 series or comparable tensile test apparatus (link)

4.1.2. Instron Bluehill software with computer

4.1.3. Instron Jaw Faces for Flats (link)

4.1.4. Lorica Soft Artificial Leather, measuring at least 6” by 6” (link)

4.1.5. Custom Lorica mount: a rigid frame with grips at the top to secure the Lorica as the frame is fixed to the base of the Instron

4.1.6. Instron Screw Side Action Grips (link)

4.1.7. Artificial Eccrine Perspiration (link)

4.1.8. Spray bottle (link)

4.1.9. Ohmmeter (link)

4.1.10. *ActivFlow Sport* device

4.1.11. *ActivFlow Sport* pad

4.1.12. *ActivFlow Sport* adhesive strips

4.1.13. Permanent marker (link)

4.2. Test 3:

4.2.1. *ActivFlow Sport* reusable pad

4.2.2. *ActivFlow Sport* adhesive strips

4.2.3. Adhesive bandages (link)

4.2.4. Printed sheet of NRS-10 (10-point Numeric Rating System for pain)

4.2.5. Printed sheet of 180 degree adhesive peel test with diagrams

5. Responsibilities

5.1. A minimum of one and maximum of two operators will be needed to perform each test.

5.2. The operator(s) of Tests 1 & 2 must be trained to use the Instron 5900 Tensile machinery and the corresponding Bluehill software.

5.3. The operator(s) of Test 3 must have CITI Certification for human subject testing and data collection.

5.4. Documentation of training will be provided for all operators and will be attached to the report of this testing.

5.5. The operator(s) will document all observations and results on a data sheet attached to the report of this testing.

6. Acceptance Criteria

6.1. For Tests 1 & 2 to be considered a success, the adhesive pad must be displaced by no more than one millimeter in any direction.

6.2. For Test 3 to be considered a success:

6.2.1. The pain caused by removing the pad should be no more than one pain level above removing an adhesive bandage on the NRS-10 pain scale;

6.2.2. The pain immediately following the removal of the pad should be no more than a 4 on the NRS-10 pain scale;

6.2.3. The pain following the removal of the pad after 30 seconds should be no more than a 2 on the NRS-10 pain scale;

6.2.4. The pain following the removal of the pad after 60 seconds should be no more than a 1 on the NRS-10 pain scale.

7. Sample Size

7.1. Sample Size for Shear Testing (Tests 1 & 2): For each test, 300 samples of the *ActivFlow Sport* adhesive system will be evaluated. Each sample will undergo 50 repetitions of applied force to simulate repeated contact during a high-impact sports game.

7.1.1. The large number of samples required for this test is justified by the high risk of medical hazard posed by internal shearing of a subcutaneous needle, as it is an effect of any movement of the external pad-device system.

7.1.2. Using variable data, with 95% confidence and 99% reliability, the minimum sample size required is 300.

7.2. Sample Size for Pain Testing: For this test, one run will be conducted on 15 different human test subjects.

7.2.1. The number of 15 test subjects is optimal for obtaining a good balance between minimizing the number of test subjects onto whom pain is inflicted and maximizing the variety of subjects' pain tolerances. Pain is relative to an individual, so the test must include a large enough sample size such that results are not skewed beyond the average pain tolerance.

7.2.2. Using variable data, with 95% confidence and 95% reliability, the minimum sample size required is 15.

8. Test Procedure

8.1. Test 1: Shear Force on Dry Skin (illustrated in Figure 1)

8.1.1. Secure Lorica Soft artificial skin to the top of the custom frame.

8.1.2. Secure the base of the custom frame to the Instron.

8.1.3. Grip Lorica sheet to lower Instron head using Jaw Faces for Flats (0 - 12.7 mm).

8.1.4. Hold *ActivFlow Sport* electronic device flush to center of Lorica Soft area.

8.1.5. Apply one-time use adhesive strips around the edges of the *ActivFlow Sport* reusable pad.

8.1.6. Secure adhesive side of pad to Lorica Soft to fully cover the electronic device area.

8.1.7. Mark initial boundaries of adhesive pad on Lorica Soft with a permanent marker.

8.1.8. Jog the upper Instron head to the device-pad area and securely grip protrusion.

8.1.9. Apply shear force via upper Instron head.

8.1.9.1. Rapidly ramp applied force from 0 Newtons to 10 Newtons in 1 millisecond.

8.1.9.2. Sustain 10 Newton force for 3 seconds.

8.1.9.3. Rapidly ramp down applied force from 10 Newtons to 0 Newtons in 1 millisecond.

8.1.9.4. Repeat this square-wave process for 50 iterations.

8.1.10. Collect displacement data of the pad-device system relative to the skin surface as a function of time.

8.2. Test 2: Shear Force on Skin with Perspiration (illustrated in Figure 1)

8.2.1. Spray Lorica Soft artificial skin with artificial perspiration.

8.2.2. Use ohmmeter to measure resistance of sprayed skin; calculate electrical conductivity from resistance value and material geometry

8.2.3. Repeat steps 8.2.1 and 8.2.2 until skin conductivity matches researched value for induced sweat during physical activity.

8.2.4. Secure Lorica Soft artificial skin to the top of the custom frame.

8.2.5. Secure the base of the custom frame to the Instron.

8.2.6. Grip Lorica sheet to lower Instron head using Jaw Faces for Flats (0 - 12.7 mm).

8.2.7. Hold *ActivFlow Sport* electronic device flush to center of Lorica Soft area.

8.2.8. Apply one-time use adhesive strips around the edges of the *ActivFlow Sport* reusable pad.

8.2.9. Secure adhesive side of pad to Lorica Soft to fully cover the electronic device area.

8.2.10. Jog the upper Instron head to the device-pad area and securely grip protrusion.

8.2.11. Apply shear force via upper Instron head.

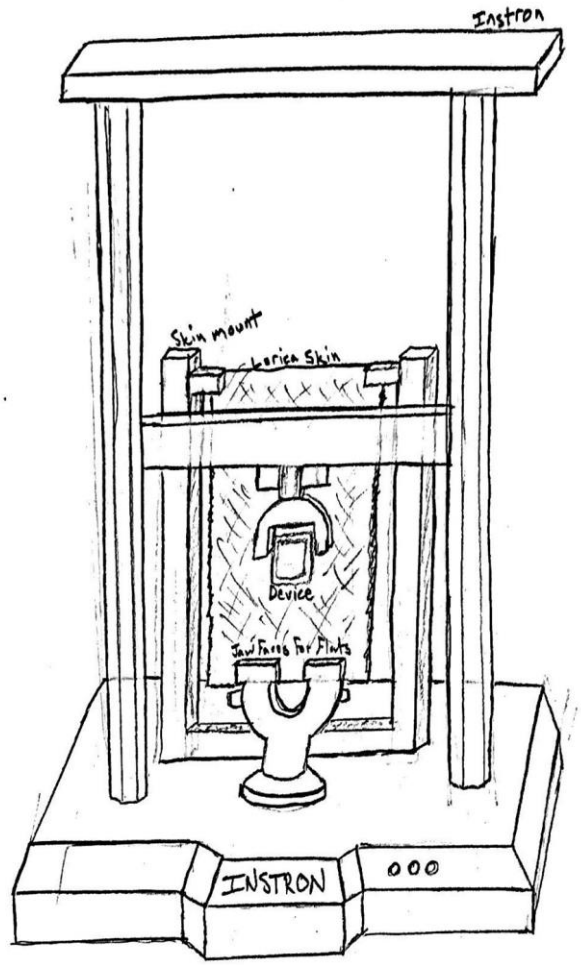
8.2.11.1. Rapidly ramp applied force from 0 Newtons to 10 Newtons in 1 millisecond.

8.2.11.2. Sustain 10 Newton force for 3 seconds.

8.2.11.3. Rapidly ramp down applied force from 10 Newtons to 0 Newtons in 1 millisecond.

8.2.11.4. Repeat this square-wave process for 50 iterations.

8.2.12. Collect displacement data of the pad-device system relative to the skin surface as a function of time.



8.3. Test 3: Reported Pain of Adhesive Removal

8.3.1. Provide human subjects with 1) standardized instructions for a 180-degree adhesive peel test and 2) a 10-point pain scale with labels (e.g., “discomforting, “tolerable”) for each numerical rating.

8.3.2. Prompt human subjects to perform bandage removal on abdomen according to instructions.

8.3.3. Record reported pain immediately after bandage removal.

8.3.4. Record reported pain 30 seconds after bandage removal.

8.3.5. Record reported pain 60 seconds after bandage removal.

8.3.6. Allow a few minutes of settling time, until human subjects relay no pain felt.

8.3.7. Apply adhesive strips to *ActivFlow Sport* reusable pad and secure firmly to human subject’s abdomen.

8.3.8. Prompt user to perform pad removal according to 180-degree adhesive peel instructions.

8.3.9. Record reported pain immediately after pad removal.

8.3.10. Record reported pain 30 seconds after pad removal.

8.3.11. Record reported pain 60 seconds after pad removal.

9. Records

9.1. All relevant training records of the Instron system and human data collection will be included in the report.

9.2. All raw data will be attached to the final report.

10. Data Sheet Format

10.1. The following test data should be included.

10.1.1. Name and signature of operator.

10.1.2. Lot numbers and traceability for all *ActivFlow Sport* components.

10.1.3. Variable result of test for each adhesive and whether it passed or failed.

10.1.4. Additional comments and observations made during testing.

10.1.5. Any deviations from the procedure should be included in the data sheets as a note.

V&V REVISION HISTORY

Revision	Effective Date	Nature of Change	Originator(s)
A	17Oct2018	Initial Release	Zachary Davenport, Ava Lakmazaheri, Emma Westerhoff