July 1, 2022

Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093 USA
ATTN: Jeanine Hembd

Reference: Report Number F2P27778-01S-R1
Subject: Test Results for Adhesion testing – pull test

Dear Ms. Hembd:

We have completed our evaluation of your Split Universal Grounding Pad, model number PAD9165L, specifically Lot # ZX20200431 to the following standard(s):

- Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories; IEC 60601-2-2, Clause 201.15.101.7 – Pull Test

Testing began on 2022-05-30 and was completed on 2022-06-10 at the F2 Labs' facility.

This report package completes all work associated with F2 Labs' project number F2P27778. Should you have any further questions regarding this letter, please feel free to contact me at 301-253-4500.

Prepared by:

Oscar P. Fuster
Project Engineer
F2 Labs

Reviewed by:

Adam Black
Safety Technical Manager
F2 Labs

Testing Summary:

Test	Clause	Result
Pull Test 1	Clause 201.15.101.7	**Pass**

Test Equipment Used:

Asset No	Description	Calibration Date	Calibration Due
0515	Scale	2021-09-27	2022-09-27
1278	Humidity/Barometer/Data Reader	2021-07-22	2022-07-22
1298	Tape Measure	2022-01-07	2023-01-07
1324	Stopwatch	2022-01-07	2023-01-07
1327	Stopwatch	2022-01-07	2023-01-07

MEDLINE NE PAD ADHESION TESTING

Protocol #: F2P27778

Purpose
The purpose of this study is to verify the performance of the neutral electrode (NE) adhesives in accordance with the testing specified in IEC 60601-2-2:2017, section 201.15.101.7, pull test.

Background
Testing the NE in accordance with IEC 60601-2-2:2017, section 201.15.101.7, is required to confirm the shelf life.

Participant Screening
After informed consent has been obtained, participants will be screened for the following inclusion and exclusion criteria.

Inclusion Criteria:

- Participants must be willing to comply with all study procedures
- Participants must be willing to shave, or to have shaved, the sites where the neutral electrodes will be placed.

Exclusion Criteria

- The participant has any skin conditions (e.g. eczema, sensitivities, allergies to adhesives, sunburn, etc.) at the application sites that might be adversely affected by the application of an adhesive pad.
- The participant is pregnant or breastfeeding.

Risks and Benefits
Possible risks associated with these tests could be an unknown sensitivity to the adhesive components. There may also be discomfort from the pulling of the pads during the Pull Test. Participants will be monitored during the testing for any adverse events.

There are no benefits to participants participating in this study.

Regulatory and Ethical Considerations

Participant confidentiality and privacy will be kept confidential per HIPAA requirements. The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party. All study data will be identified with an anonymous participant number, and all CRFs and other documents containing data will have the participant number and no identifiable information. One master list linking participant numbers to participant name and other contact information will be maintained by the staff in the event identification of a participant is necessary. This is the only documentation that will link participant name and participant number.

Study staff will ensure all source documents for data collection are completed in accordance with Good Documentation Practices (GDP) in order to ensure accurate interpretation of data.

All study records will be maintained for a minimum of two years following study closeout; records will be maintained for a longer period of time as required by IRB or other regulations.

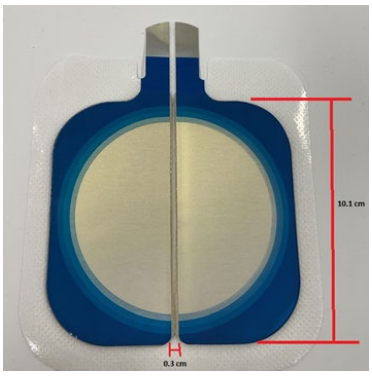
Deviations

It is the responsibility of the PI and study staff to use continuous vigilance to identify and report deviations on a routine basis. All deviations must be addressed in study source documents, and reported to Medline Industries, LP. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

Device Under Test Description

Model:	PAD9165L, Lot # ZX20200431	Pad, Grounding, Split, 15’ Cord
Dimensions:	12.0cm x 13.4cm	
Total area:	160.8 cm^2	
Total conductive area:	96.2– 3.03* = 93.17 cm^2	
	*inside dimension of non-conductive area per photo	

Photo of Pad:



Medline's Split Universal Grounding Pads are intended for use in monopolar electrosurgery to complete the electrosurgical circuit between the generator, the active electrode, and the patient. The pads are single use, non-sterile, dispersive electrodes with or without a pre-attached cord. The surface of the conductive area is covered with a soft, conformable hydro-gel conductive adhesive. The pad also has a nonwoven backing and a non-conductive border adhesive surrounding the entire conductive surface area to isolate the conductive area from surgical fluid. The Universal Pads are designed for use in duty cycles of 50% or less (e.g. 20 sec on followed by 20 sec off).

Instructions for Use

Select an Appropriate Site

To reduce the risk of burns and pressure necrosis:

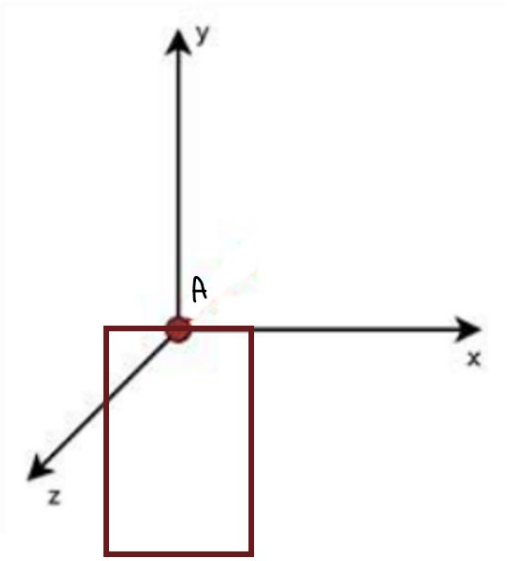
- Select a smooth, well-vascularized, muscular area close to surgical site that allows full Universal Pad-to-skin contact.
- Site must be clean, dry, and free of hair. Remove hair at application site.
- Locate Universal Pad closer to the surgical site than to the ECG electrodes.
- Remove metal jewelry.
- Avoid placement over bony prominences, metal prostheses, or scar tissue.
- Avoid placement such that current flows through a metal prosthesis or conductive implant. For patients with implanted electronic devices, contact device manufacturer for precautions to avoid interference.
- Do not apply Universal Pad where fluids may pool.
- Do not apply Universal Pad over injection site.
- Select a suitable site remote from any warming device.

4. **Pad Application**

To reduce the risk of burns and pressure necrosis:

- Inspect Universal Pad, cord, and cable. Do not use if cut, modified, or damaged.
- Remove clear liner from Universal Pad before applying to patient.
- Apply one end of Universal Pad and smoothly press to the other end. The entire surface of the pad should be in contact with the patient. Avoid air entrapment.
- Avoid stretching or folding either Universal Pad or patient's skin.
- Do not wrap Universal Pad completely around a limb. Do not overlap.
- Do not attempt to relocate Universal Pad after initial application. If patient is repositioned, confirm full pad-to-skin contact and integrity of all connections.
- Do not use electrode gel.
- Do not place cable clamp under patient.
- Do not coil or wrap cord or cable around limb or metal object.
- Do not place compression stocking or device over grounding pad.

Figure 1 – NE Pad



NE Pad, dimensions 12.0cm x 13.4cm

xy plane is skin surface

Point A (0,0,0) is NE Cord connection point

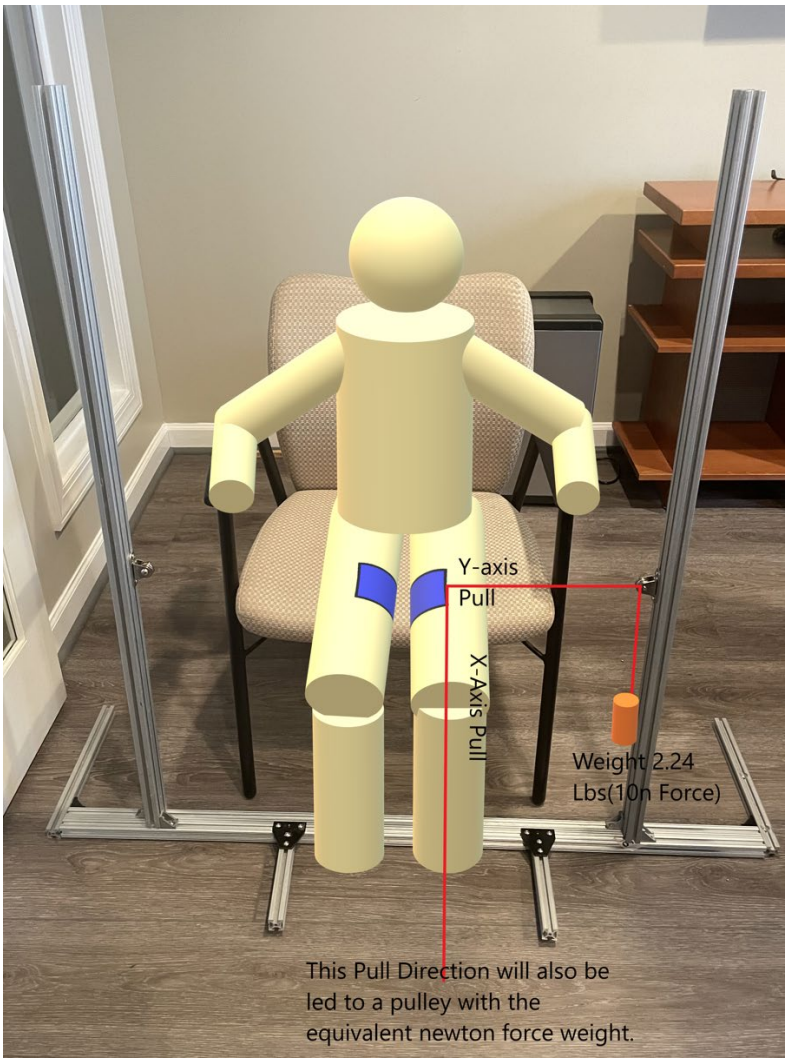
x-ray direction for pull test

y-ray direction for pull test

IEC 60601-2-2 Clause 201.15.101.7 NE Adhesion – Pull Test

Test Method: At least two samples of the NE under test are applied to convenient locations on at least 10 male and 10 female human subjects, according to instructions for use. After application, NEs are allowed to remain undisturbed for 5 min to 10 min. For NEs intended for use on adult PATIENTS, the attached NE cord is subjected for 10 min to a 10 N force directed along each of two orthogonal axes in a plane parallel to the skin surface at the NE cord connection point. One of the axes shall consist of the minor dimension of the NE at that point. No more than 5 % of the NE adhesive area shall separate from the skin surface in at least 90 % of the tests.

Figure 2, Test Setup:



Preparation for testing

Sanitize participant area at least ½ hour before the arrival of any study participant.

Ensure all equipment to be used is calibrated or verified before using.

For NE placement, remove all hair from these locations if not already done. Then clean and dry the sites thoroughly.

Cut the cables of the neutral electrodes (NEs) at a point at least 20cm from the NE. Then tie a loop in the cables for connection to the cords.

Apply two NEs on the ventral surfaces of the upper leg of the participant, in a sitting position, such that the edge of the NE with the cable exit is aligned along the midline of the upper leg and parallel to the floor (with the upper leg approximately parallel to the floor). When applying NEs apply one end and smoothly press to other end. The entire surface of the NE should be in contact with the participant. Avoid air entrapment under NE.

Have the participant sit still, with the NE undisturbed, between 9 to 10 minutes.

Pull test instructions, see Figure 1 and Figure 2

Record Participant number.

Record Sample number.

At Point A where the NE connects to the pad, connect a cord to pull on the cable as indicated in figure 2 below. Pull for 10 to 10.25 minutes, in a plane parallel to the NE pad and in a direction away from the center of the pad, with 10 to 11N (1.02 to 1.12kg) of force in the direction along the minor dimension of the pad. Set the height of the pulley so that the direction of pull shall be approximately co-planer with the plane of the connection point of the NE. The pull shall be performed by a cord connected to the NE at the cable connection point. See Figure 2 for the pull set up. The weights provide the required pull force.

Start timer.

At 10 mins, change direction of pull to y direction by rotating the pulley system 90 degrees as shown in Figure 2 – apply 10 to 11 N force at Point A in direction of y ray which is in a plane parallel to the pad.

Start timer.

At 10 mins:

photograph NE pad

record the % of the NE adhesive area that has separated.

Repeat the above steps on a second NE pad for each Participant (these tests could be done in parallel if desired with duplicate setup).

Test Engineer: Oscar P. Fuster
Reviewed by: Adam Black

Pull Test							
Participant #	**Leg applied to**	**Sample #**	**Room Temperature, C**	**Room Humidity, %**	**Time elapsed (undisturbed), min sec**	**% of NE Pad separated, %**	**Verdict (Pass/ Fail)**
1	Left	S6	22.6	56.6	9:23	0	Pass
1	Right	S20	22.6	56.6	9:58	0	Pass
2	Left	S31	20.1	53.8	9:15	0	Pass
2	Right	S32	20.1	53.8	9:45	0	Pass
3	Left	S37	23.6	45.2	9:01	0	Pass
3	Right	S22	23.6	45.2	9:38	0	Pass
4	Left	S13	24.8	50.4	9:39	0	Pass
4	Right	S12	24.8	50.4	9:11	0	Pass
5	Left	S10	23.6	47.0	9:50	0	Pass
5	Right	S11	23.6	47.0	9:12	0	Pass
6	Left	S8	23.6	47.3	9:33	0	Pass
6	Right	S9	23.6	47.3	9:58	0	Pass
7	Left	S21	22.8	56.2	9:31	0	Pass
7	Right	S19	22.8	56.2	9:52	0	Pass
8	Left	S4	22.5	60.1	9:05	0	Pass
8	Right	S3	22.5	60.1	9:32	0	Pass
9	Left	S1	22.5	60.1	9:18	100, pad separated at 2:29 of x direction (Y - axis could not be done)	Fail
9	Right	S2	22.5	60.1	9:49	0	Pass
10	Left	S7	22.6	56.6	9:30	0	Pass
10	Right	S5	22.6	56.6	9:52	0	Pass
11	Left	S23	20.9	57.7	9:21	0	Pass
11	Right	S24	20.9	57.7	9:51	1.8	Pass
12	Left	S25	20.9	57.7	9:04	0	Pass
12	Right	S26	20.9	57.7	9:28	0	Pass
13	Left	S28	22.1	51.2	9:50	0	Pass
13	Right	S27	22.1	51.2	9:25	0	Pass
14	Left	S29	22.1	51.2	9:42	0	Pass
14	Right	S30	22.1	51.2	9:15	0	Pass
15	Left	S14	24.3	49.1	9:01	0	Pass
15	Right	S15	24.3	49.1	9:33	0	Pass
16	Left	S16	24.3	49.1	9:45	0	Pass
16	Right	S17	24.3	49.1	9:14	0	Pass
17	Left	S39	24.3	49.1	9:15	0	Pass
17	Right	S40	24.3	49.1	9:20	0	Pass
18	Left	S18	24.3	49.1	9:51	0	Pass
18	Right	S38	24.3	49.1	9:22	0	Pass
19	Left	S34	23.3	54.8	9:01	0	Pass
19	Right	S33	23.3	54.8	9:33	0	Pass
20	Left	S35	23.3	54.8	9:15	0	Pass
20	Right	S36	23.3	54.8	9:52	0	Pass

Pull Test

Pass/Fail Criteria: No more than 5% of the NE adhesive area shall separate in at least 90% of the tests.
Test Summary: Total Tests: 40 # Tests where no more than 5% of the NE adhesive area separated: 39 % of Total tests where no more than 5% of the NE adhesive area separated: 97.5% Result: PASS
Supplementary information:(assets per test): 1298, 1324, 1327, 1278, 0515

Photo of Sample S24 with 1.8 % Separation: