



Omni-Wave™ 3-day Study White Paper

Comparative 3-day clinical study of Flexcon® Omni-Wave™ technology versus common hydrogel based monitoring electrode solutions.

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Introduction

Electrocardiograms (ECG) are performed every day to measure the electrical activity of the heart on patients of all ages and skin types. Through electrode patches that adhere to the patient's skin, doctors can diagnose heart attacks and identify anomalies of the heart. These electrodes may be worn anywhere from a few minutes to multiple days in cases where it is important to track the heart's activity over time. The most common electrodes used are hydrogel based which come with key performance pitfalls. Flexcon developed Omni-Wave™ technology to provide clinicians and patients with an alternative electrode adhesive that overcomes the common issues seen with hydrogel materials.

Hydrogels are the incumbent technology used for electrodes, but there are several issues with hydrogel-based materials. Firstly, hydrogel materials can cause skin reactions in approximately 8% of patients. Hydrogels are also affected by environmental conditions, such as heat and humidity. Hydrogels can pick up or lose water if not stored properly which has the potential of modifying several performance aspects of the material. In addition to a potential negative user experience, the use of hydrogels can be potentially wasteful as they typically have a short out-of-pack shelf life. Finally, from a manufacturing and processing perspective, hydrogels require both expensive barrier packaging to prevent a change in water content and specialized equipment for converting the bulky hydrogels into finished goods, all of which increase the cost of these materials.

In contrast to hydrogels, Flexcon's Omni-Wave™ is a dry conductive adhesive technology that does not rely on water to function. Omni-Wave™ utilizes polar additives and low resistance materials to allow it to convey bio-electric signals.

From a technical perspective, the polar additive is miscible with Flexcon's adhesive system and is selected to allow it to maintain adhesion for the desired timeframe. The additives do not disrupt the function of the adhesive and are non-irritating to the skin.

Background

A clinical trial was designed to compare Omni-Wave™ electrodes vs. competitive hydrogel based electrodes for electrode conductivity, skin irritation, and adhesion.

For this trial, a set of 12 participants wore three sets of Omni-Wave™ electrodes and standard competitive hydrogel electrodes.

Patient baseline characteristics:

- Sex: 6 male / 6 female
- Age: Aged 28-78 years old with average age of 50.7 years old
- Race: 10 white / 2 Asian

Electrode sets were placed next to each other with one set on the chest, one set on the arm and one set on the leg. On day one, baseline EKG readings were taken with both the Omni-Wave™ and competitor electrodes. Subjects were instructed to make no changes in lifestyle and were able to continue their daily routines, including showering and exercising. The subjects were also instructed to remove the electrodes if they experience significant skin irritation, such as blisters or a burning sensation. Additionally, if electrodes fell off during the course of the study, they were instructed to reapply to the same spot if possible. On day three, final EKG readings were taken and each subject was assessed for skin irritation, adhesion quality, and discomfort level during removal.

Results

All twelve subjects were active in the study at the conclusion of the three-day test period and assessed as follows:

- Signal / Electrode conductivity: No discrepancies in EKG tracings were identified between day 1 and day 3 for all 12 participants for either Omni-Wave™ or the competitor.
- Skin irritation: All subjects were able to tolerate both Omni-Wave™ and competitive hydrogel electrode. No severe adverse skin reactions were identified; however red marks and itchiness were experienced on some patients (Table 1, Image 1).

Table 1: Number of subjects who experienced skin irritation, N=12

	Omni-Wave™	Competitive hydrogel electrode
Red Marks	2	7
Itchiness	0	1

Discomfort during removal:

- Subjects noted that the Omni-Wave™ electrodes were more comfortable to remove and did not cause a waxing-like pain that was experienced with the competitive product. Additionally, all subjects noticed dirt residue around the edge of the competitive electrode that was difficult to remove (Image 2).



Conclusion

Both Omni-Wave™ and the competitive hydrogel electrodes were shown to have comparable excellent conductivity on Day 1 and Day 3, while subjects were able to maintain routine lifestyle without any restrictions, including shower or exercise. Omni-Wave™ appears to cause less skin irritation than the competitor electrodes as Omni-Wave™ leaves no red marks, does not cause skin itchiness, leaves no dirt residual around the edge, and it is easy for removal without causing any pain. Less adhesion was seen in Omni-Wave™ when compared to the competitive electrode after 3 days of wear. Noticeably, young subjects tend to experience worse adhesion quality than older subjects, which may be associated with activity level and perspiration condition. Overall, Omni-Wave™ electrodes provided both a positive patient experience and comparable electrical performance to hydrogel-based electrodes in this clinical trial.

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