# COVER FOR ELECTROMAGNETIC TREATMENT APPLICATOR

## Cross-Reference to Related Applications

This application claims the benefit of provisional application no. 60/154,435, filed September 17, 1999.

## Field of the Invention

The present invention relates to electromagnetic treatment devices, and more particularly to an apparatus for covering an electromagnetic energy treatment applicator which protects the applicator from biohazards and provides selective radio frequency (RF) shielding.

## Background of the Invention

Electrotherapy includes various means of applying an electric or electromagnetic field to a wound area to facilitate growth and proliferation of new tissue, i.e., healing. In an earlier patent application filed by the present inventors, an electromagnetic treatment device is disclosed. The device includes a pulsed electromagnetic energy generator, a power level controller and one or more applicators. Each applicator is a pad comprising one or more etched copper printed circuits laminated between insulating sheets of material having high dielectric properties. Sensing units, including an electromagnetic signal strength detector and an applicator-to-patient proximity detector, are incorporated in each applicator and are in communication with the power level controller to provide for direct monitoring of the electromagnetic energy field and precise control of the treatment dosage. The applicators, which are constructed in a variety of shapes and sizes to best match the wound size and area

on the patient, are placed over, under or around a bandaged wound site. Since the applicators are not disposable items, needs exist for apparatus which prevent cross-contamination between patients.

In addition, electromagnetic treatment applicators remain in direct contact with the wound site during treatment. Thus, the patient, and possibly the health care providers, are potentially exposed to the emitted radiation. Needs exist for apparatus which limit undesired exposure of the patient and health care provider to the treatment radiation.

Existing covers for radiation shielding and medical applications are unacceptable for use with electromagnetic treatment applicators, such as the one described above. Typical covers for use in medical applications are disclosed in U.S. Patent Nos. 3,942,023, 4,605,124 and 4,715,366. Examples of other devices which provide radiation shielding are disclosed in U.S. Patent Nos. 5,336,896 and 5,523,581. Needs exist for covers for electromagnetic treatment applicators which are cost effective, disposable and easy to use.

Citation of the above documents is not intended as an admission that any of the foregoing is pertinent prior art. All statements as to the date or representation as to the contents of these documents is based on the information available to the applicants and does not constitute any admission as to the correctness of the dates or contents of these documents. Further, all documents referred to throughout this application are incorporated in their entirety by reference herein.

**Summary of the Invention**

It should be apparent that there exists a need for facilitating the safe and effective treatment of patients with electromagnetic energy. It is therefore a primary object of the present invention to fulfill that need by providing a cost effective, easy to use, disposable cover for use with an electromagnetic energy treatment applicator. The present cover is easy to affix to the treatment applicator, assists in easy application of the applicator to the patient, promotes the transmission of RF energy waves to the patient while blocking the propagation of those waves in any other direction, and provides biohazard shielding for protecting against the transmission of diseases between patients. Further, the cover is configured in a manner which integrates the electromagnetic properties of the cover into the circuitry for the treatment applicator, such that the applicator is not functional in the absence of the cover, thereby providing additional safeguards that the intended treatment is safe and efficacious.

More particularly, the present invention is a disposable cover for devices that are used for therapeutically treating humans with dosages of electromagnetic energy. The cover includes RF shielding material oriented toward the backside of the cover, opposite the treatment area. At least a portion of the cover which faces the treatment area is constructed solely from non-shielding material. Securing means, such as adhesive strips, ZIP-LOCK®, or other interlocking edges, are provided for securing the applicator inside the cover and closing off any leaks. The cover also includes portions which wrap around the cord leading from the applicator to the generating unit.

In use, an electromagnetic treatment applicator is inserted into the present cover and positioned over the area to be treated, with the non-shielding, or "window", portion of the

cover overlying the treatment area. In one embodiment, the dimensions of the "window" are formed by removing selected strips from the outer surface of the cover. Once assembled, the applicator/cover combination forms a closely matched and tuned network for effecting a highly efficient RF output. When activated, the generated electromagnetic energy only exits the cover through the opening or "window", thereby preventing exposure of the patient or caregiver to potentially harmful radiation.

The present invention has immediate commercial market potential in the field of chronic wound healing. Beyond that immediate market, the present invention may also be utilized in other treatment fields where increasing the rate of growth and proliferation of human or other living cells is essential, including the treatment of burns and surgically implanted skin or soft tissue grafts, sports and rehabilitation medicine, post surgical repair, and neuronal/brain/spinal injury repair and regeneration. In addition to the medical treatment of soft tissue, the present invention has applications in the field of laboratory growth/manufacturing of skin grafts to be sold and used in various surgical settings, veterinary medicine and related fields.

These and further and other objects and features of the invention are apparent in the disclosure, which includes the above and ongoing written specification, with the drawings.

**Brief Description of the Drawings**

FIG. 1 is a plan view of the disposable cover;

FIG. 2 is a block diagram showing how the cover is configured to integrate its electromagnetic properties into the circuitry of the applicator; and

FIG. 3 is a plan view of the disposable cover with mating interlocking structures.

**Detailed Description of the Invention**

Referring now to the drawings, where like elements are designated by like reference numerals throughout, FIG. 1 shows an apparatus, more fully described below, for covering an electromagnetic energy treatment applicator. Apparatus 1 includes a front sheet 3 and a back sheet 5. Edges of the sheets 3, 5 are sealed or otherwise connected to form a pouch-like structure with an open end 7 for receiving an applicator (not shown). In alternative embodiments, the apparatus 1 is made from a single sheet, which is folded and sealed such that it has an open end 7. The front sheet 3 (which faces the treatmcnt area) is preferably made, at least partially, of a non-shielding material, such as transparent polyethylene. The back sheet 5 (which faces opposite, or away from, the treatment area) is preferably constructed entirely from shielding material, such as metallized polyethylene, thereby ensuring the blockage of unintended RF transmissions in nontreatment directions. One or more light adhesive strips are located along the outer surface of the front sheet 3 for affixing the cover 1 to a bandage. Preferably, the front sheet 3 of the cover 1 has a patch of adhesive at its center for securing the applicator over the treatment area. The selected adhesive is of low bonding force enabling easy separation from the mating surface.

As shown in FIG. 1, a tab portion 11 extends from the front sheet 3. After the applicator is inserted in the cover 1 through its open end 7, tab portion 11 is folded over such that it overlies a section of the outer surface 13 of the back sheet 5. In one embodiment, an adhesive strip 15 is provided along the outer surface 13 of the back sheet 5 for securing the tab portion 11 in its folded position. In another embodiment, tab portion 11 has a permanent adhesive strip which preferably runs the length of the unsealed end. It

should be understood that other attachment means for securing the tab portion 11 in its folded position are contemplated by the present invention. Preferably, tab portion 11 includes a semi-circular notch 17 or other similar opening or spacing which allows a coaxial cable to protrude therethrough when the cover 1 is sealed. Tab portion 11 further includes perforations 19, preferably provided along the length of the tab portion 11, for enabling easy removal. It should also be understood that, in yet another embodiment, tab portion 11 consists of a ZIP-LOCK® strip or other interlocking means to connect it to a second tab portion extending along the top of front sheet 3. (FIG. 3)

For additional biohazard protection, the tab portion 11 is extended, thereby allowing the tab portion 11 to be wrapped around the cable. In such embodiments, no notch is required. Rather, the extended tab portion 11 is wrapped around the cable and secured thereto with adhesive located along a surface of the tab portion. The tab portion is also secured to the back sheet 5 to seal off entry to the interior of the cover 1 where the applicator is located.

It should be understood that the tab portion 11 can extend from the back sheet 5, as opposed to the front sheet 3, or from both the back sheet 5 and the front sheet 3 without departing from the scope of the present invention. Other means for sealing off the open end of the cover 1, including, but not limited to, mating tabs, ZIP-LOCK® strips, or other fastening means, are also contemplated by the present invention.

In an alternative preferred embodiment, shown in FIG. 3, tab portions extend from both the front sheet 3 and the back sheet 5. Mating interlocking means 12, such as ZIP-LOCK® strips, are located along each tab portion 11.

In its preferred form, the cover 1 is rectangular in shape and approximately 10

inches by 12 inches in size. The thickness of the cover 1 is approximately 1/100 of an inch. At least the outer surface of the cover 1 is water proof and bacterial resistant, and is designed to be placed directly on the patient or on top of any standard dressings used over the area to be treated.

As described earlier, the cover 1 is composed of a combination of two types of materials - one selected for its properties of resistance to transmission of RF waves and one selected for its ability to be mechanically joined to the first material. Both materials are preferably also good barriers to moisture absorption, thereby preventing biohazards from coming in contact with the applicator surfaces. The RF shielding material prevents emission from the applicator in any direction other than that to be focused at the wound site. The shielding enables the use of the electromagnetic treatment device while being compliant with standards for transmission of radio frequency and other forms of electromagnetic energy.

In its simplest form, the front sheet 3 is made of a non-shielding material and the back sheet 5 is made of a shielding material. It should be understood, however, that variations of this embodiment are also contemplated by the present invention. For example, the entire cover can be constructed of RF shielding material except for a window over the treatment zone (the treatment zone is characterized as the area above the applicator transmitting antenna). In an alternative embodiment, the entire cover, or a portion thereof, can be constructed of non-shielding material, with strips of shielding material adhered thereto. For example, RF shielding material perforated in concentric circles, or other shapes, are bonded to the outer surface of the transparent material. In such embodiments, the window over the treatment zone can be variable in size, with the user able to peel off

certain shielding strips to match the transmission region to that of the wound to be treated. Other variations area also considered within the scope of the present invention.

In preferred embodiments, proper placement of the cover 1 over the applicator is required for the device to operate. Preferably, the applicator (such as the one disclosed in the present applicants' earlier patent application) incorporates RF shielding material as a capacitor which is part of the electronic tuning of the applicator. Without the cover, the applicator cannot be tuned, thus the electromagnetic energy treatment device will detect a fault and will not operate. In one embodiment, as shown in FIG. 2, cover 1 includes a shielded side which conveys a particular capacitance upon the circuitry enclosed within the applicator. When the requisite capacitance is present, the applicator sends an appropriate voltage signal to a previously described power generator device (described in earlier application filed by inventors), enabling the device. In the absence of the cover conveying the requisite capacitance, the voltage signal remains outside of a predetermined range and the power generating device is disabled. In other words, the RF shielding provided by the cover acts as an additional source of capacitance (Y) which changes the final capacitance of system (Z). The RF generating system is adjusted such that it is only operable when the capacitance is within the range provided by the capacitance within the internal applicator pad shield circuitry (X) plus the capacitance (Y) provided by the cover.

The present invention is operated by placing the treatment applicator into the cover through its open end, with the treatment side of the applicator oriented towards the front sheet and the coaxial cable of the applicator protruding through the open end. A permanent adhesive peel strip (which is located on the tab portion or the back sheet) is removed, exposing the adhesive. Tab portion is folded over the end of the applicator, with the semi-

circular cutout notch aligned with the coaxial cable. The tab portion is then pressed against the back sheet to fully close the cover.

Where the cover includes an extended tab portion, there is no semi-circular cable cutout. Rather the extended tab portion is folded over and wrapped around the coaxial cable and bonded together to form a biohazard barrier. For further securement, a portion of the tab portion also adheres to the back sheet.

Next, the peel strip material is removed from the outer surface of the front sheet to expose a low bonding force adhesive. The covered applicator is aligned with the wound site. Indicia, such as printed designs, may be located on the outer surface of the front sheet for facilitating proper alignment. The cover is then adhered to the bandaged wound site, thus ensuring proper location of the applicator to the wound site. The adhesive is not permanent and can easily be pulled away from the bandaged site.

Following treatment, the cover is removed from the applicator and properly disposed. Preferably, removal of the cover involves the following steps. First, the cover is gripped at the two corners away from the end with the protruding coaxial cable. Pulling the corners in opposite directions causes the cover to tear at the center. As the tear clears the cover can be removed from the applicator and disposed. For embodiments including the extended tab portion, the user continues the tear the cover past the intersection of the applicator and cable until the cover can be removed.

From the foregoing, it will be appreciated by those skilled in the art that the present invention provides a particularly effective and advantageous method of and apparatus for overcoming many of the limitations associated with the treatment of patients using electromagnetic energy. It will also be readily appreciated by one with ordinary skill in the

art to use the method and apparatus of the present invention in other applications, such as veterinary applications.

Although certain presently preferred embodiments of the present invention have been specifically described herein, it will be apparent to those skilled in the art to which the invention pertains that variations and modifications of the various embodiments shown and described herein may be made without departing from the spirit and scope of the invention.

## CLAIMS

We claim:

1. An apparatus for covering a treatment applicator comprising a cover having a front surface, a back surface, and at least one open end, wherein at least a portion of said cover is constructed of an RF shielding material.

2. Apparatus according to claim 1, wherein said back surface of said cover is constructed of said RF shielding material.

3. Apparatus according to claim 2, wherein at least a portion of said front surface of said cover is constructed of said RF shielding material.

4. Apparatus according to claim 1, wherein said RF shielding material is metallized polyethylene.

5. Apparatus according to claim 1, further comprising at least one adhesive strip located on said front surface.

6. Apparatus according to claim 1, further comprising means for closing said open end of said cover.

7. Apparatus according to claim 6, wherein said closing means further comprises a tab extending from said front surface and means for securing said tab to said back surface.

8. Apparatus according to claim 7, wherein said securing means is selected from the group consisting of adhesive, mating fasteners and mating ZIP-LOCK® strips.

9. Apparatus according to claim 7, wherein said tab has an opening located therein.

10. Apparatus according to claim 9, wherein said opening is a semi-circular notch.



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11. Apparatus according to claim 7, further comprising perforations located along said tab.

12. Apparatus according to claim 6, wherein said closing means further comprises a tab extending from said back surface and means for securing said tab to said front surface.

13. Apparatus according to claim 6, wherein said closing means further comprises a first tab extending from said front surface, a second tab extending from said back surface, and means for securing said first tab to said second tab.

14. Apparatus according to claim 1, wherein said cover is waterproof and bacterial resistant.

15. An apparatus for covering a treatment applicator comprising a cover having a front surface, a back surface, at least one open end, and at least one strip of RF shielding material removable connected to said cover.

16. Apparatus according to claim 15, wherein said front surface is made of a non-shielding material, wherein said at least one strip overlies said front surface, and wherein said at least one strip further comprises a perforated strip.

17. Apparatus according to claim 15, wherein said at least one strip is removably adhered to the front surface.

18. Apparatus according to claim 15, wherein said at lest one strip further comprises multiple strips, each adhered to the front surface of the cover and separably removable therefrom.

19. An electromagnetic treatment apparatus comprising an RF generating system, a



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cover, and an applicator connected to said RF generating system and located within said cover, wherein said cover further comprises RF shielding that conveys a capacitance upon circuitry in said applicator.

20. Apparatus according to claim 19, wherein said applicator only enables said RF generating system when said applicator is located within said cover and a capacitance of said applicator and cover is within a predetermined range.

