Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
Description

Field

[0001] This invention relates, generally, to the heat treatment of a biological site in a human or animal body. More particularly, the invention relates to a system for, and a method of, heating a biological site in a patient’s body to produce at least one lesion at the site or for the treatment of pain management.

Background

[0002] Electromagnetic energy, in the form of radio frequency (RF) energy, is used to produce lesions at a biological site in the human or animal body for many purposes such as, for example, for cardiac ablation purposes, for tumour ablation, etc. RF energy can also be used for heating a site for the treatment of pain management. To apply the RF energy at the required site in the body, an electrode is used as a conductor with an electrode tip forming a first terminal of the circuit and a back patch beneath the patient’s body forming a return electrode for the circuit so that, when the electrode tip is brought into contact with the site, a closed circuit is formed. A problem with this arrangement is that the impedance of the patient’s body is high resulting in dissipation of the RF energy through the patient’s body rather than being concentrated at the site.

[0003] Traditionally lesions have been produced at a site using a single active electrode system. The RF energy is applied to a small electrode tip towards the end of a catheter with a return path being made via the patient’s body.

[0004] US Patent No. 6,485,487 discloses an apparatus for delivering energy to a biological site. The apparatus includes a catheter having a plurality of electrodes positioned proximal the biological site. A power control system supplies power to each electrode. Where an electrode or group of electrodes is turned off, the power control system provides a high impedance to the turned off electrodes so that substantially no current flows to those electrodes from other electrodes that may remain on. This permits the turned off electrodes to cool. The power control system may permit control over the phase and duty cycle of the power applied to the electrodes and may permit individual control over the power provided to each electrode. A backplate is also positioned proximal the biological site so that the biological site is interposed between the electrodes and the backplate. Where a unipolar/bipolar approach is used with the backplate, the power control system controls the phase angle of the power applied to the electrodes so that the current flows between the electrodes and between the electrodes and the backplate.

Summary

[0005] According to a first aspect of the invention, there is provided a system for heating a site in a patient’s body, the system including a transformer having a primary winding and a secondary winding, the secondary winding having at least one tap to provide a patient reference and at least two sources of radio frequency (RF) energy, the two sources of RF energy being out of phase with each other; and a group of electrodes connected to the sources of RF energy provided by the secondary winding to be simultaneously energised, the arrangement being such that there are more active electrodes connected to one of the sources of RF energy than the other of the sources of RF energy with the energy supplied to one active electrode being out of phase with the energy supplied to an adjacent active electrode.

[0006] At least periodically, the group of active electrodes may comprise an odd number of electrodes with a sub-group of an even number of active electrodes being connected to one of the sources of RF energy and a sub-group of an odd number of active electrodes being connected to the other of the sources of RF energy and the active electrodes of the sub-groups alternating with one another along a length of a catheter carrying the electrodes. More particularly, the group of electrodes may comprise at least three active electrodes which are energised simultaneously with the energy supplied to one sub-group comprising two outer electrodes of the group of three active electrodes being in phase with each other but out of phase with the energy supplied to another sub-group comprising a single, inner, or middle, active electrode arranged between the two outer electrodes of the one sub-group.

[0007] The system may include a switching arrangement interposed between the secondary winding of the transformer and the group of electrodes periodically to change the configuration of active electrodes connected to the sources of RF energy.

[0008] It will be appreciated that it is not necessary that it is always the same active electrode that is connected to the one sub-winding. In practice, this may not in fact be the case. For example, in a 3 electrode system, electrode 1 may initially be connected to the first sub-windings and electrode 3 may be connected to the second sub-winding. After a predetermined period of time, electrodes 1 and 3 may be connected together to the first sub-winding under the action of the switching arrangement and electrode 2 may be connected to the second sub-winding.

[0009] The system may include a monitoring device associated with each electrode for monitoring the energy supplied to each active electrode. The monitoring device may be a temperature sensing device, such as a thermocouple or thermistor, for monitoring the temperature of its associated active electrode. In addition, monitoring devices may also be arranged between adjacent elec-
[0012] The transformer may have a 1:1 ratio between the primary winding and the secondary winding. The tap may be a centre tap to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other.

[0017] At least one active electrode may be connected to one sub-winding and at least two active electrodes may be connected to the other sub-winding.

**Brief Description of the Drawings**

[0018] Fig. 1 shows a schematic block diagram of an embodiment of a system for heating a biological site in a patient’s body, the system being shown in a first configuration; and

Fig. 2 shows a schematic block diagram of the system in a second configuration.

**Detailed Description of Exemplary Embodiments**

[0019] In the drawings, reference numeral 10 generally designates a system, in accordance with an embodiment of the invention, for heating a site in patient’s body. The system 10 includes a generator 12 for generating electromagnetic energy, more particularly, radio frequency (RF) energy.

[0020] The generator 12 is in communication with a transformer 14. The transformer 14 has a core 14.1, a primary winding 14.2 and a secondary winding 14.3. The secondary winding 14.3 of the transformer 14 is a centre tapped transformer having a centre tap 16. The centre tap 16 is connected via a return line 18 to the generator 12.

[0021] The centre tap creates two sub-windings 22, to each of which at least one active electrode 24 of a catheter 26 is connectable. By “active” is meant that, unless the context clearly indicates otherwise, the electrode is used to impart energy to the site.

[0022] The arrangement of the sub-windings 22 is such that, due to the centre tap 16, energy supplied by one sub-winding 22 is 180° out of phase with the energy supplied by the other sub-winding 22.

[0023] The transformer 14 makes use of a 1:1 ratio between the primary winding 14.2 and the secondary winding 14.3. In addition, the materials used in the transformer 14 are selected to be capable of withstanding energy levels and frequencies involved in ablative therapies. The transformer 14 and the materials used are optimised to ensure maximum transfer of energy from the

[0011] The transformer may have a 1:1 ratio between the primary winding and the secondary winding. The tap may be a centre tap to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other.

[0012] In an embodiment, at least one of the electrodes connected to each source of RF energy may not be active at the time that at least one other electrode connected to that source of RF energy is active.

[0013] According to a second aspect of the invention, there is provided a system for heating a site in a patient’s body, the system including a transformer having a primary winding and a secondary winding, the secondary winding having at least one tap to provide a patient reference and at least two sources of radio frequency (RF) energy, the two sources of RF energy being out of phase with each other; and a plurality of active electrodes connected to the sources of RF energy provided by the secondary winding to be simultaneously energised, with multiple active electrodes being connected to one of the sources of RF energy and a different number of active electrodes being connected to the other source of RF energy and the energy supplied to each of the multiple active electrodes being of the same phase but out of phase with the energy supplied to each of the different number of active electrodes.

[0014] The amplitude of the energy supplied to each of the multiple active electrodes may be less than the amplitude of the energy supplied to each of the different number of active electrodes.

[0015] The system may include an energy generator for generating the RF energy, the primary winding of the transformer being connected to an output of the energy generator. The generator may be responsive to the switching arrangement and to a monitored parameter of the electrodes, as monitored by a monitoring device associated with each electrode, to control the RF energy supplied to the electrodes. The monitored parameter of each electrode may be a temperature of each electrode. Thus, the monitoring device associated with each electrode may be a temperature sensing device, such as a thermocouple or thermistor.

[0016] The transformer may have a 1:1 ratio between the primary winding and the secondary winding. The tap may be a centre tap to provide two sub-windings which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other.

[0017] At least one active electrode may be connected to one sub-winding and at least two active electrodes may be connected to the other sub-winding.
transformer 14 to the active electrodes 24.

[0024] Suitable materials for the transformer include nickel-zinc or manganese-zinc ferrites for the core 14.1 of the transformer 14, in particular F8, F12 and F14 ferrites. These materials are able to operate at the required frequencies and have the necessary high initial permeability and high saturation flux. The dimension of the core, the number of turns of the windings 14.2 and 14.3 and the diameter of the windings are selected so that the transformer 14 has low insertion losses to ensure efficient transfer of energy.

[0025] The primary winding 14.1 of the transformer 14 is matched to the output impedance of the generator 12. The generator 12 has an output impedance of between about 30 and 300 ohms. If necessary, a series resistor and/or a parallel capacitor can be included to effect impedance matching.

[0026] The active electrodes 24 are connected to the secondary winding 14.3 of the transformer 14 via a switching arrangement 28. In addition, each active electrode 24 has a thermocouple, illustrated schematically by each line 30, connected to the switching arrangement for the control of energy to the active electrodes 24 by the system 10. The system 10 also includes a thermocouple 30 connected between adjacent electrodes 24 for more accurate temperature control.

[0027] The system 10 is intended for use in the production of lesions at a site in a patient’s body for treating various disorders such as atrial fibrillation, ventricular tachycardia, tumour ablation, or the like or for heat treating the site in the treatment of pain management. In the case of pain management, it may not be necessary that lesions are actually created, rather that heat treating of the site effects management of the pain.

[0028] In the case of atrial fibrillation, abnormal electrical impulse activity in the tissue gives rise to irregular heart rhythms. This necessitates the formation of a large number of spot lesions. This is a time consuming and difficult process and may result in excessive charring of the tissue. It is also necessary that the spots overlap to ensure that the undesirable signal path is interrupted. Thus accurate placement of the ablating electrode of a catheter is required. Also, use is made of a back plate as a return electrode resulting in excessive dissipation of energy through the patient’s body.

[0029] If it were possible to form longer lesions, the number of lesions to be formed can be reduced thereby improving the accuracy of the technique and minimising damage to the tissue.

[0030] In use, in an initial configuration, the electrodes 24 are connected to the secondary winding 14.3 of the transformer 14 in the configuration shown in Fig. 1 of the drawings. Thus, a sub-group comprising two outer electrodes 24 of a group of three electrodes 24 is connected to one of the sub-windings 22 with a sub-group comprising the inner electrode 24 of the group of three electrodes 24 being connected to the other sub-winding 22. The energy supplied to each outer electrode 24 is half that of the energy supplied to the inner electrode 24. In addition, the energy supplied to the outer electrodes 24, while being in phase with each other, is out of phase with the energy supplied by the sub-winding 22 to the inner electrode 24. More particularly, the energy supplied to the outer electrodes 24 is 180° out of phase with the energy supplied to the inner electrode 24.

[0031] While this embodiment has been described with reference to the use of three active electrodes 24, it will be appreciated that any desired number of electrodes could be used. For example, a five active electrode system would have electrodes 1, 3 and 5 connected to one of the sub-windings 22 with a phase angle of the energy of 0° with electrodes 2 and 4 being connected to the other sub-winding 22 with a phase angle of the energy of 180°.

[0032] Using this arrangement of energising alternate electrodes of a group of electrodes, a longer, more confluent lesion is formed which concentrates the ablation extending between inner ends of the outer electrodes 24 of the group of electrodes. The connection of electrodes 1 and 3 to the same phase is done using the switching arrangement 28 and may incorporate a relay or a mechanical switch.

[0033] In a variation of this embodiment, the switching arrangement 28 includes a timing mechanism. Initially, energy is supplied to the site using the three active electrodes 24 (in this example) in the configuration shown in Fig. 1 of the drawings. After a predetermined period of time, the switching of the electrodes changes so that electrode 1 is connected to one of the sub-windings 22 and electrode 3 is connected to the other sub-winding 22 with electrode 2 not being connected to either sub-winding 22. With this arrangement, an even longer, confluent lesion is formed which extends over the entire length of the distance covered by the three electrodes. In other words, a lesion is formed up to outer ends of the outer electrodes 24 with a very rectangular appearance and a more uniform depth than with a traditional, single electrode system.

[0034] The system 10 could also have a number of inactive electrodes connected to each sub-winding of the transformer 14. Thus, in another embodiment, a cascading-like effect can be imparted to a series of electrodes 24 for creating a longer lesion but with lower power consumption. Thus, for example, if one sub-winding 22 had three electrodes 24 connected to it and the other sub-winding had two electrodes connected to it, the switching arrangement 28 could be configured to energise only three electrodes 24 at any one time. In this embodiment, one active electrode 24 of one sub-winding 22 is interposed between two active electrodes both connected to the other sub-winding 22 so that the energy supplied to the middle active electrode 24 is 180° out of phase with the energy supplied to the two outer electrodes 24. The remaining electrodes 24 connected to the sub-windings are not energised and are inactive.

[0035] Thus, electrodes 1 and 3 connected to the first sub-winding and electrode 2 connected to the second
A system (10) for heating a site in a patient's body, comprising a transformer (14) having a primary winding (14.2) and a secondary winding (14.3), the secondary winding (14.3) having at least one tap (16) to provide a patient reference and at least two sources (22) of radio frequency (RF) energy, the two sources (22) of RF energy being out of phase with each other, and a group of electrodes (24) connected to the sources (22) of RF energy provided by the secondary winding to be simultaneously energised, characterized in that the arrangement is such that there are more active electrodes (24) connected to one of the sources (22) of RF energy than the other of the sources.

Claims

1. A system (10) for heating a site in a patient's body, the system including a transformer (14) having a primary winding (14.2) and a secondary winding (14.3), the secondary winding (14.3) having at least one tap (16) to provide a patient reference and at least two sources (22) of radio frequency (RF) energy, the two sources (22) of RF energy being out of phase with each other, and a group of electrodes (24) connected to the sources (22) of RF energy provided by the secondary winding to be simultaneously energised, characterized in that the arrangement is such that there are more active electrodes (24) connected to one of the sources (22) of RF energy than the other of the sources.
(22) of RF energy with the energy supplied to one active electrode (24) being out of phase with the energy supplied to an adjacent active electrode (24).

2. The system (10) of claim 1 in which, at least periodically, the group of electrodes (24) comprises an odd number of active electrodes (24) with a sub-group of an even number of active electrodes (24) being connected to one of the sources (22) of RF energy and a sub-group of an odd number of active electrodes (24) being connected to the other of the sources (22) of RF energy and the active electrodes (24) of the sub-groups alternating with one another along a length of a catheter carrying the electrodes (24).

3. The system (10) of claim 2 in which the group of electrodes (24) comprises at least three active electrodes (24) which are energised simultaneously with the energy supplied to one sub-group comprising two outer active electrodes (24) of the group of three electrodes (24) being in phase with each other but out of phase with the energy supplied to a sub-group comprising a single, inner active electrode (24) arranged between the two outer electrodes (24) of said one group.

4. The system (10) of any one of the preceding claims which includes a switching arrangement (28) interposed between the secondary winding (14.3) of the transformer (14) and the group of electrodes (24) periodically to change the configuration of electrodes (24) connected to the sources (22) of RF energy.

5. The system (10) of claim 4 which includes a monitoring device (30) associated with each electrode (24) for monitoring the energy supplied to each active electrode (24).

6. The system (10) of claim 5 in which the monitoring device (30) is a temperature sensing device for monitoring the temperature of its associated active electrode (24).

7. The system (10) of claim 5 or claim 6 in which the monitoring devices (30) are connected to the switching arrangement (28), the switching arrangement (28) being responsive to a parameter of each active electrode (24), monitored by its associated monitoring device (30), for feedback control of the magnitude of RF energy to be supplied to the electrodes (24) and/or for switching between configurations of electrodes (24) connected to the sources of RF energy (22).

8. The system (10) of any one of claims 4 to 7 which includes an energy generator (12) for generating the RF energy, the primary winding (14.2) of the transformer (14) being connected to an output of the energy generator (12).

9. The system (10) of claim 8 in which the generator (12) is responsive to the switching arrangement (28) and to the monitored parameter of the active electrodes (24), as monitored by the monitoring devices (30), to control the RF energy supplied to the active electrodes (24).

10. The system (10) of any one of the preceding claims in which the transformer (14) has a 1:1 ratio between the primary winding (14.2) and the secondary winding (14.3).

11. The system (10) of any one of the preceding claims in which the tap (16) is a centre tap to provide two sub-w windings (22) which act as energy sources with the energy supplied by the sources being 180° out of phase with respect to each other.

12. The system (10) of any one of the preceding claims in which at least one of the electrodes (24) connected to each source (22) of RF energy is not active at the time that at least one other electrode (24) connected to that source (22) of RF energy is active.

Patentansprüche

1. System (10) zum Erwärmen einer Stelle in einem Patientenkörper, wobei das System umfasst:

einen Transformatör (14) mit einer Primärwicklung (14.2) und einer Sekundärwicklung (14.3), wobei die Sekundärwicklung (14.3) wenigstens einen Abgriff (16) besitzt, um eine Patientenreferenz und wenigstens zwei Quellen (22) für Hochfrequenzenergie (HF-Energie) zu schaffen, wobei die zwei HF-Energiequellen relativ zueinander phasenverschoben sind; und

eine Gruppe von Elektroden (24), die mit den HF-Energiequellen (22) verbunden sind und durch die Sekundärwicklung versorgt werden, um gleichzeitig erregt zu werden, dadurch gekennzeichnet, dass die Anordnung derart ist, dass mehr aktive Elektroden (24) mit einer der HF-Energiequellen (22) als mit der anderen der HF-Energiequellen (22) verbunden sind, wobei die Energie, die einer aktiven Elektrode (24) zugeführt wird, zu der Energie, die einer benachbarten aktiven Elektrode (24) zugeführt wird, phasenverschoben ist.

2. System (10) nach Anspruch 1, wobei die Gruppe von Elektroden (24) zumindest periodisch eine ungerade Anzahl aktiver Elektroden (24) umfasst, wobei eine Untergruppe mit einer geraden Anzahl aktiver Elektroden (24) mit einer der HF-Energiequellen (22) ver-

4. System (10) nach einem der vorhergehenden Ansprüche, die eine Schaltanordnung (28) umfasst, die zwischen die Sekundärwicklung (14.3) des Transformators (14) und die Gruppe von Elektroden (24) eingefügt ist, um die Konfiguration der mit den HF-Energiequellen (22) verbundenen Elektroden (24) periodisch zu ändern.

5. System (10) nach Anspruch 4, das eine Überwachungsvorrichtung (30) umfasst, die jeder Elektrode (24) zugeordnet ist, um die jeder aktiven Elektrode (24) zugeführte Energie zu überwachen.

6. System (10) nach Anspruch 5, wobei die Überwachungsvorrichtung (30) eine Temperaturerfassungsvorrichtung ist, um die Temperatur ihrer zugeordneten aktiven Elektrode (24) zu überwachen.

7. System (10) nach Anspruch 5 oder Anspruch 6, wobei die Überwachungsvorrichtungen (30) der Schaltanordnung (28) verbunden sind, wobei die Schaltanordnung (28) auf einen Parameter jeder aktiven Elektrode (24) anspricht, der durch ihre zugeordnete Überwachungsvorrichtung (30) überwacht wird, um eine Rückkopplungssteuerung für die Größe der HF-Energie auszuführen, die den Elektroden (24) zugeführt wird, und/oder um zwischen Konfigurationen von Elektroden (24), die mit den HF-Energiequellen (22) verbunden sind, zu schalten.

8. System (10) nach einem der Ansprüche 4 bis 7, das einen Energiegenerator (12) umfasst, um die HF-Energie zu erzeugen, wobei die Primärwicklung (14.2) des Transformators (14) mit einem Ausgang des Energiegenerators (12) verbunden ist.

9. System (10) nach Anspruch 8, wobei der Generator (12) auf die Schaltanordnung (28) und auf den überwachten Parameter der aktiven Elektroden (24), der durch die Überwachungsvorrichtungen (30) überwacht wird, anspricht, um die den aktiven Elektroden (24) zugeführte HF-Energie zu steuern.

10. System (10) nach einem der vorhergehenden Ansprüche, wobei der Transformator (14) ein 1:1-Verhältnis zwischen der Primärwicklung (14.2) und der Sekundärwicklung (14.3) besitzt.

11. System (10) nach einem der vorhergehenden Ansprüche, wobei der Abgriff (16) ein Mittelabgriff ist, um zwei Unterwicklungen (22) zu schaffen, die als Energiequellen wirken, wobei die von den Quellen zugeführte Energie relativ zueinander um 180° phasenverschoben ist.

12. System (10) nach einem der vorhergehenden Ansprüche, wobei wenigstens eine der Elektroden (24), die mit den einzelnen HF-Energiequellen (22) verbunden sind, während der Zeit, in der wenigstens eine andere Elektrode (24), die mit der HF-Energiequelle (22) verbunden ist, aktiv ist, nicht aktiv ist.

Revendications

1. Un système (10) pour le traitement thermique d’un site dans le corps d’un patient, le système incluant un transformateur (14) ayant un bobinage primaire (14.2) et un bobinage secondaire (14.3), le bobinage secondaire (14.3) ayant au moins une prise (16) pour fournir une référence du patient et au moins deux sources (22) d’énergie à radiofréquence (RF), les deux sources (22) d’énergie RF étant déphasées une par rapport à l’autre, et un groupe d’éléctrodes (24) connectées aux sources (22) d’énergie RF fournie par le bobinage secondaire, destiné à être alimenté simultanément, caractérisé en ce que l’agencement est tel qu’il y a plus d’éléctrodes actives (24) connectées à au moins deux sources (22) d’énergie RF qu’aux autres sources (22) d’énergie RF, l’énergie fournie à une éléctrode active (24) étant déphasée par rapport à l’énergie fournie à une électrode (24) active adjacente.

2. Le système (10) selon la revendication 1, dans lequel, au moins périodiquement, le groupe d’éléctrodes (24) comprend un nombre impair d’éléctrodes (24) actives, un sous-groupe d’un nombre pair d’éléctrodes (24) actives étant connecté à une des sources (22) d’énergie RF et un sous-groupe d’un nombre impair d’éléctrodes (24) actives étant connecté à l’autre source (22) d’énergie RF, et les électrodes (24) actives des sous-groupes alternant les unes avec les autres le long d’un cathéter portant les électrodes (24).

3. Le système (10) selon la revendication 2, dans lequel...
le groupe d’électrodes (24) comprend au moins trois électrodes (24) actives qui sont alimentées simultanément, l’énergie fournie à un sous-groupe comprenant deux électrodes (24) extérieures actives du groupe de trois électrodes (24) étant en phase les unes par rapport aux autres mais déphasées par rapport à l’énergie fournie à un sous-groupe comprenant une électrode (24) active, unique et intérieure, agencée entre les deux électrodes extérieures dudit groupe.

4. Le système (10) selon l’une des revendications précédentes, qui inclut un agencement de commutation (28) intercalé entre le bobinage secondaire (14.3) du transformateur (14) et le groupe d’électrodes (24) périodiquement pour changer la configuration des électrodes (24) connectées aux sources (22) d’énergie RF.

5. Le système (10) selon la revendication 4, qui inclut un dispositif de surveillance (30) associé à chaque électrode (24) pour surveiller l’énergie apportée à chaque électrode (24) active.

6. Le système (10) selon la revendication 5 dans lequel le dispositif de surveillance (30) est un dispositif de détection de température permettant de surveiller la température de son électrode (24) active associée.

7. Le système (10) selon la revendication 5 ou la revendication 6, dans lequel les dispositifs de surveillance (30) connectés à l’agencement de commutation (28), l’agencement de commutation (28) étant réactif à un paramètre de chaque électrode (24) active, surveillé par son dispositif de surveillance (30) associé, pour une commande en retour de la grandeur de l’énergie RF devant être fournie aux électrodes (24) et/ou pour une commutation entre des configurations des électrodes (24) connectées aux sources d’énergies RF (22).

8. Le système (10) selon une des revendications 4 à 7, qui inclut un générateur d’énergie (12) pour générer l’énergie RF, le bobinage primaire (14.2) du transformateur (14) étant connecté à une sortie du générateur d’énergie (12).

9. Le système (10) selon la revendication 8, dans lequel le générateur (12) est réactif à l’agencement de commutation (28) et au paramètre surveillé des électrodes (24) actives, tel que surveillé par les dispositifs de surveillance (30), pour commander l’énergie RF fournie aux électrodes (24) actives.

10. Le système (10) selon l’une des revendications précédentes, dans lequel le transformateur (14) a un ratio 1:1 entre le bobinage primaire (14.2) et le bobinage secondaire (14.3).
REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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