METHOD AND APPARATUS FOR ENDOMETRIAL TREATMENT

Abstract: A treatment device for treating endometrial tissue, comprising: an elongate housing defining an axis, the housing incorporating or having attached thereto a projection for abutting, in use, a body portion associated with the endometrial tissue; a treatment applicator extending axially from the housing and incorporating a (e.g. microwave) radiation emitting element; an electronically controllable actuator (e.g. linear stepper), coupled to the housing and to the treatment applicator; wherein the actuator is adapted to move the treatment applicator axially relative to the housing by a predetermined step distance (e.g. corresponding to the axial length of the radiation emitting element) along said axis in response to a step control signal. Thus, through sweeping movements of the housing, successive bands of endometrial tissue are treated. In other embodiments, angular (rate) and position sensing, and bending displacement sensing, enables control of the power applied to the tissue. Treatment systems, and corresponding methods of treatment, are also disclosed.
Method and apparatus for endometrial treatment

The present invention relates to techniques for the treatment of the human body, and more particularly to techniques for the treatment of endometrial tissue.

This invention concerns devices, systems and methods designed to improve the safety and efficacy of endometrial ablation. Endometrial ablation is a widely used technique for destroying the lining of the womb to prevent or reduce menstrual bleeding. It can be performed using microwaves, radio-frequency currents, hot fluids, hot fluids enclosed in a balloon, and other techniques.

The invention is, for example, particularly beneficial in relation to microwave endometrial ablation.

A problem with known systems is that they do not facilitate positional and motional control of the ablative (heating) element, e.g. the emitting tip of a microwave ablative applicator.

A further problem is that, while transverse position and sweeping motion of an applicator within a uterus can be implemented by hand, existing systems do not permit accurate integrated control of axial position in conjunction with this motion.

A further problem is that, in relation to treatment applicators that are swept, during treatment, through an angle (due to the shape of the uterus) so as to cover the breadth of the uterine wall, known systems do not permit use of angular position and angular rate of motion of an applicator (tip) in the treatment process.

A further problem is that existing systems do enable use of multi-dimensional angular position/rate data.

A further problem is that known techniques do not provide enhanced detection of the lateral extremities of the endometrial tissue to be treated.

According to one aspect of the invention there is provided a treatment device for treating endometrial tissue, comprising: an elongate housing defining an axis, the housing incorporating or having attached thereto a projection for abutting, in use, a body portion associated with the endometrial tissue; an elongate member extending...
axially from the housing and incorporating a radiation emitting element; an electronically controllable actuator, coupled to the housing and to the elongate member; wherein the actuator is adapted to move the elongate member axially relative to the housing by a predetermined step distance along said axis in response to a step control signal.

Preferably, the projection comprises a collar shaped for abutting, in use, the cervix or the internal os.

Preferably, said predetermined step distance is approximately equal to the axial length of said radiation emitting element.

The actuator may be fixedly mounted on the interior of the housing and adapted to move the elongate member into and out of the housing, or the actuator may be fixedly mounted on the elongate member and adapted to move the elongate member into and out of the housing.

Preferably, the actuator comprises a stepping linear actuator.

The treatment device may further include a sensor, fixed to the housing and/or to the elongate member, for providing a signal indicative of the position of the elongate member or of the radiation emitting element relative to the housing or relative to a calibration point. Preferably, the treatment device further includes circuitry for providing a signal indicative of the distance from the housing or from a calibration point to the radiation emitting element or to a part of the elongate member.

Preferably, the treatment device further includes circuitry for providing a signal indicative of the angle relative to a calibration axis of the axis of the elongate member.

According to another aspect of the invention there is provided a treatment system for treating endometrial tissue, comprising: the treatment device of any of claims 1 to 8 of the appended claims; and a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and a controller, coupled to the radiation source and to the treatment device, for transmitting the step control signals and/or controlling the supply of energy to the radiation emitting element.
Preferably, the controller includes at least a processor and memory, the processor being operable in conjunction with memory for (a) receiving said position signals, distance signals and/or angle signals indicative of the position, distance from a calibration point or angle, respectively, of the radiation emitting element; (b) in dependence upon the received position signals, distance signal and/or angle signals, transmitting a step control signal to the treatment device, whereby the elongate member is moved axially by said predetermined step distance, for example corresponding to the axial length of said radiation emitting element. Preferably, the system is operable to treat the tissue in successive substantially arcuate bands extending between the sidewalls of the endometrium; and wherein the processor is operable in conjunction with memory for generating said step control signal when it is determined from said position signals, distance signals and/or angle signals that the radiation emitting element has passed over and thereby treated the entire area of tissue within a band.

According to another aspect of the invention there is provided a method of treating endometrial tissue, comprising: providing a treatment device according to any of claims 1 to 8 of the appended claims; sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue within a substantially arcuate band extending between the sidewalls of the endometrium; and during said sweeping, periodically or aperiodically transmitting a step control signal to the treatment device, whereby the elongate member is moved axially by said predetermined step distance by said linear actuator; thereby treating the endometrial tissue in successive bands.

According to another aspect of the invention there is provided a treatment device for treating endometrial tissue, comprising: an elongate housing defining an axis; an elongate member extending axially from the housing and incorporating a radiation emitting element; a first angular rate sensor, for detecting the angular rate of sweeping of the elongate element through rotation thereof about an axis transverse to the axis of the housing, and providing an angular rate signal indicative of said angular rate.

Alternatively, the device comprises, instead of a first angular rate sensor, a first angular sensor, for detecting the angular position of the elongate element in a plane
parallel to the axis of the housing and relative to a first calibration axis, and providing an angular position signal indicative of said angular position.

The treatment device may further comprise a second angular rate sensor, for detecting the angular position of the elongate element in a second plane perpendicular to the axis of the housing and relative to a second calibration axis, and providing a second angular position signal indicative of said angular position in said second plane.

According to another aspect of the invention there is provided a treatment system for treating endometrial tissue, comprising: the treatment device of claim 13 of the appended claims; circuitry, coupled to receive the angular rate signal and generate a first control signal if said angular rate signal meets predetermined criteria and/or generating a second control signal if said angular rate signal does not meet said predetermined criteria.

Preferably, said circuitry is adapted to determine the minimum angular rate over a period; and said predetermined criteria include the determined minimum angular rate being above a predetermined threshold. The treatment system preferably further includes circuitry for storing a first calibration value, said first calibration value being the signal output by the first angular rate sensor when the elongate member is stationary, and/or for storing a second calibration value, said second calibration value being the signal output by the second angular rate sensor when the elongate member is stationary.

Preferably, the treatment system further includes circuitry for integrating said angular rate signal thereby deriving the angular position of the elongate member relative to a calibration orientation.

According to another aspect of the invention there is provided a treatment system for treating endometrial tissue, comprising: the treatment device of claim 14 or 15 of the appended claims; and circuitry, coupled to receive the angular position signal(s) and generate a control signal if said angular position signal(s) meets predetermined criteria.

According to another aspect of the invention there is provided a treatment system, comprising: the treatment device of any of claims 13 to 15 of the appended claims; a
radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and a controller, coupled to the radiation source and to the treatment device, for transmitting control signals and/or controlling the supply of energy to the radiation emitting element.

The treatment system preferably further comprises circuitry for providing a signal indicative of the distance from the housing or from a calibration point to the radiation emitting element or to a part of the elongate member; wherein the controller includes a processor, memory and user interface (UI). Preferably, the processor is operable in conjunction with memory for (c) logging position signals, distance signals and/or angle signals indicative of the position, distance from a calibration point or angle, respectively, of the radiation emitting element; and (d) displaying in the UI a graphical representation of the endometrium, the graphical representation including (i) areas of the endometrium that have not been treated, (ii) areas of the endometrium that have been treated, and/or (iii) the current position within the endometrium of the radiation emitting element. Preferably, (d) comprises displaying in different colours and/or with different shades each of said (i) areas of the endometrium that have not been treated, (ii) areas of the endometrium that have been treated, and/or (iii) current position within the endometrium of the radiation emitting element. Preferably, the processor is operable in conjunction with memory for (e) receiving radiation power signals, indicative of the instantaneous power of the radiation emitted by the radiation emitting element; and (f) in dependence upon said (A) radiation power signals and (B) position signals, distance signals and/or angle signals, displaying, in the areas of the uterus that have been treated, elemental parts thereof in a colour corresponding to the amount of thermal or other energy applied thereto by the radiation emitting element.

According to another aspect of the invention there is provided a method of treating endometrial tissue, comprising: providing a treatment device according to any of claims 13 to 15 of the appended claims; sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue in a substantially arcuate band extending between the sidewalls of the endometrium; and controlling the supply of energy to the radiation emitting element in dependence upon at least the sensed angular rate or angular position of the elongate member.
According to another aspect of the invention there is provided a method of treating endometrial tissue, comprising: providing a treatment system according to claim 22 of the appended claims; sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue in a substantially arcuate band extending between the sidewalls of the endometrium; and operating the processor in conjunction with memory to (g) log position signals, distance signals and/or angle signals indicative of the position, distance from a calibration point or angle, respectively, of the radiation emitting element; and (h) display in the UI a graphical representation of the endometrium, the graphical representation including (i) areas of the endometrium that have been treated, (ii) areas of the endometrium that have been treated, and/or (iii) the current position within the endometrium of the radiation emitting element.

According to another aspect of the invention there is provided a treatment device for treating endometrial tissue, comprising: an elongate housing defining an axis; an elongate member extending axially from the housing and incorporating a radiation emitting element; wherein at least part of the elongate member is made of a resilient material whereby, in use, the elongate member may bend away from said axis; and wherein the device further includes a transverse displacement sensor for providing a displacement signal indicative of the extent of bending of said elongate member.

The transverse displacement sensor may comprise at least one strain gauge mounted in or on the elongate member. Alternatively, the transverse displacement sensor may comprise a plurality of strain gauges, the strain gauges being mounted circumferentially around the exterior of the elongate member.

Alternatively, the treatment device may further comprise a tube partially enclosing the elongate member; wherein the transverse displacement sensor comprises a switch formed at least partially by elements at one end of the tube that may be engaged, in use, by the elongate member. Preferably, the elements comprise first electrical contacts, the elongate member includes second electrical contacts on the side thereof, wherein, in use, abutment of said first and second electrical contacts when the bending of the elongate member has reached a predetermined extent closes a switch, thereby generating said displacement signal.
According to another aspect of the invention there is provided a treatment system for treating endometrial tissue, comprising: the treatment device of any of claims 28 to 32 of the appended claims; a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and a controller, coupled to the radiation source and to the treatment device, for transmitting control signals and/or controlling the supply of energy to the radiation emitting element.

Preferably, the controller includes at least a processor and memory, and wherein the processor is operable to in conjunction with memory to (i) receive said displacement signal from the transverse displacement sensor; and (ii) adjust the supply of energy to the radiation emitting element when said displacement signal indicates the extent of bending of said elongate member is above a predetermined bending threshold. Preferably, (ii) comprises cutting the supply of energy to the radiation emitting element when said displacement signal indicates the extent of bending of said elongate member is above a predetermined bending threshold.

According to another aspect of the invention there is provided a method of treating endometrial tissue, comprising: providing a treatment system, the treatment system comprising the treatment device of any of claims 28 to 32 of the appended claims, a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and a controller, coupled to the radiation source and to the treatment device, for transmitting control signals and/or controlling the supply of energy to the radiation emitting element, wherein the method comprises: sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue in a substantially arcuate band extending between the sidewalls of the endometrium; and operating the controller to (iii) receive said displacement signal from the transverse displacement sensor; and (iv) adjust the supply of energy to the radiation emitting element when said displacement signal indicates the extent of bending of said elongate member is above a predetermined bending threshold.

Various aspects of the invention provide advantages, including the following.

(a) Ease of use: as withdrawal is performed automatically, it makes the treatment easier to perform.
(b) Safety: the applicator can only extend to the fundus of the uterine cavity, reducing the chance of a perforation. In conjunction with the sidewall sensors perforation detection is facilitated.

(c) Efficacy: since the withdrawal is automated, and the rate of motion monitored/measured, enhanced efficacy is facilitated by ensuring consistent coverage of the cavity.

Other benefits and advantages of the invention will be apparent from the description hereinafter and/or to persons skilled in the art.

Embodiments of the invention will now be described in detail, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a schematic illustration of the uterus, whose tissue is treated according to embodiments of the invention;
Figure 2 is a partial view of a treatment device according to an embodiment of the invention, disposed within the uterus;
Figure 3 depicts a polar coordinate system used in determining the position of the treatment device of Fig. 2;
Figure 4 is a perspective view of a treatment device according to a second embodiment of the invention;
Figure 5 is a partial view of a treatment device according to a third embodiment of the invention;
Figure 6 illustrates bands of tissue within the uterus that are treated by one embodiment of the invention;
Figure 7 shows the treatment device of Fig. 2 during treatment of a specific band of tissue;
Figure 8 shows the treatment device of Fig. 2 during treatment of a specific band of tissue; and
Figure 9 shows the treatment device of Fig. 2 during treatment, at the end of a band and contacting the sidewall of the uterus;
Figure 10 is a partial view of a treatment device according to a fourth embodiment of the invention, (a) in unstressed state, and (b) subject to maximum lateral bending;
Figure 11 shows the treatment device of Fig. 2 during treatment, embedded in the end wall of the uterus;
Figure 12 is a partial view of a treatment device according to a fifth embodiment of the invention, showing parts enclosed in a reusable handle;
Figure 13 is a view of a treatment device of Fig. 12, showing the cervical collar;
Figure 14 shows a map of the uterine cavity generated in a graphical display by the treatment system according to an embodiment of the present invention;
Figure 15 is an updated version of the map of Fig. 14, showing (shaded) the areas of the uterus wall that have been treated; and
Figure 16 is a schematic illustration of the overall treatment system in accordance with embodiments of the invention; and
Figure 17 shows flow charts schematically illustrating the derivation, according to certain embodiments of the invention, of angular position, axial extension (distance), and x,y positions of the tip 210.

In the description and drawings, like numerals are used to designate like elements. Unless indicated otherwise, individual features and components may be used in combination with other disclosed features.

Treatment devices and treatment systems for performing endometrial ablation, as well as methods of treatment, will hereinafter be described. The techniques described herein may make use of microwaves, radio-frequency currents, hot fluids, hot fluids enclosed in a balloon, and other techniques, as the heat generation/application means. The present invention will be described with reference to a microwave-based system, but other modalities could be used. Thus, as used herein "radiation emitting element" is to be interpreted as any element capable, directly or indirectly, of causing heating of tissue.

In accordance with the invention, in microwave endometrial ablation, a cylindrical applicator is inserted into the womb (the uterine cavity). Microwave energy is then applied and microwaves radiate from the applicator tip into the tissue causing it to heat. The tissue temperature is measured using a thermocouple on the surface of the applicator, and this is used as a control parameter. The applicator is swept from side to side manually until a tissue temperature of 70-80 degrees C has been reached. When this temperature has been reached evenly over the area being treated, the applicator is manually withdrawn slightly, and the process repeated. The embodiments of the invention as described below are based on achieving treatment without reference to temperature; however, optionally, temperature at the tip may be measured and used as a control parameter in addition to the enhancements set out below.
Figure 1 is a schematic illustration of the uterus, whose tissue is treated according to embodiments of the invention. The uterus 100 has an internal cavity 102, of generally triangular shape, at the base of which is the internal os 104. The internal os 104 is the restricted opening into the uterine cavity 102 at the end of the cervix 106. The internal os 104, which is rather like a very tight thick rubber grommet, must be dilated to allow a treatment applicator (not shown) to pass through. The uterus' internal cavity 102 includes back wall 107, sidewalls 108 and end wall 110.

Figure 2 is a partial view of a treatment device 200 according to an embodiment of the invention, partially disposed within the uterus 100. The treatment device 200 incorporates an elongate treatment applicator 202 that protrudes from, and is able to move axially relative to, an opening 204 in a collar section 206 of a housing 208, which is in turn relatively elongate. The applicator 202 incorporates a tip 210, for example a microwave heating element, for applying microwave energy to, and thereby heating, the tissue of the uterus cavity 102.

**Mechanical Withdrawal**

Figure 3 depicts a polar coordinate system used in determining the position of the treatment device of Fig. 2. The location of any point P in a plane can be specified relative to any other point (e.g. origin O), by an angle and a distance. This is the basis of the polar coordinate system. As shown, knowledge of the angle \( \theta \) of the point P relative to the central line 302, together with its distance \( r \) from the origin O, allows the location of P to be determined.

Referring to Figs 1 to 3, this method of locating position has, as discovered by the inventors, the potential to be applied to the uterine cavity 102, with the distance measured relative to the internal os 104, and/or the cervix 106, and the angle measured relative to the mid-line of the patient. Knowing the depth of the applicator 202 into the patient, together with relative angle allows the position of the applicator tip 210 to be calculated.

Continuous information on the location of the applicator tip 210 together with a known power output for the applicator 202 allows an energy dose to be calculated for the tissue (or elemental area thereof) at any point, thus giving accurately reproducible heating depths for the treatment being performed.
The applicator 202 that applies the heat passes through the entrance to the cavity (in the case of the uterus 100 this is the cervix 106 and internal os 104). The applicator 202 is then movable relative to the housing 208 that in turn has a fixed position relative to the cavity. In the example shown in Fig. 2, the housing 208 incorporates a (cervical collar) 206 section that butts up against the cervix 106 to fix the position of the applicator 202 relative to the cavity 102. The applicator 202 is then driven, in and out of the housing 208, and controlled by a linear actuator (not shown; discussed below) that is linked to a system (not shown) that controls the position of the applicator 202. This allows the distance of the applicator tip 210 to be known relative to the cervix 106. In an alternative embodiment, rather than a large cervical collar 206, the housing 208 may incorporate a tubular section (not shown in Figs 1 to 3) that is narrow enough to pass through the cervix 106, but not through the internal os 104. In this case the distance between the applicator tip 210 and the internal os 104 is known.

In order to ensure that the fixed unit (cervical collar 206 or tubular section that fits into the internal os 104) is in place, a force sensor (not shown) may be built into the abutting surface of the cervical collar 206 or tubular section, to ensure pressure is being applied to the cervix 106 at all times. A signal from this force sensor is fed back to the system (control electronics; not shown) and gives additional safety by causing the system to cut power to the applicator 202 if the fixed unit surrounding the applicator 202 is moved back away from the cervix 106 or internal os 104. A suitable a force sensor is a strain gauge.

Pre-treatment, the depth d of the fundus (Fig 2) is measured relative to the internal os 104, and the distance between the cervix 106 and the internal os 104 may also be measured. This may be performed by sounding, or through ultrasound, or other imaging methods.

Figure 4 is a perspective view of a treatment device according to a second embodiment of the invention. In this embodiment, the treatment device 200 includes a tubular section 402 and a conically tapering section 404 between the collar 206 and the applicator 202. The applicator 202 (attached an inner rod 406), is able to move in the direction of arrows A, into and out of the housing 208, through aperture 204.

Figure 5 is a partial, highly schematic cross-sectional view of a treatment device according to a third embodiment of the invention. In this embodiment, an arm 502 is
rigidly attached to the inner rod 406. To move the applicator 202 in the direction of arrows A (i.e. between successive sweeps or between treatment of successive bands of the back wall 107 of the uterus (see Fig. 1), a linear actuator 504 (which is fixedly attached to the housing 208 on its outer wall, and is electrically coupled to the system controller; not shown), acts on the arm 502. However, it will be appreciated that in an alternative embodiment the linear actuator 504 may be fixedly mounted on the rod 406 and act upon an arm or other part fixedly attached to the housing 208.

Equally, in an alternative embodiment, the actuator 504 may be mounted so as to drive the cervical collar (206; Fig. 4) forward, rather than pulling the applicator 202 back. In other words, either the applicator 202 can be retracted relative to the collar 206, or the collar 206 can be advanced so that the applicator 202 is retracted into it.

An example of a suitable linear actuator 504 a stepping linear actuator available from McLennan Servo Supplies, part number L921.11-P1, and from Radio Spares, part number 340-6467.

Optionally, in order to ensure additional safety, a feedback system may be used to check the position of the applicator 202 (or cervical collar 206). This may be done using a potentiometer, an optical motion sensor (see WO2006/005579), or other well-known techniques for measuring position. In the case of safety potentiometers, the potentiometers are mounted to sense the relative movement, so in one case the potentiometer body (not shown) would be mounted on the handle (housing 208) with the slider (not shown) attached to the moving collar 206. In the other case, the potentiometer body would be on the handle (housing 208) with the slider on the moving applicator shaft (rod 406).

This aspect invention (mechanical withdrawal of the applicator 202) has two benefits: firstly, in relation to safety, to prevent over-insertion of the applicator, and secondly efficacy, to give a consistent and predetermined dose of thermal energy to the tissue to be treated.

Figure 6 illustrates successive bands of tissue within the uterus that are treated by one embodiment of the invention. The bands 602 comprise strips of the wall(s) of the uterine cavity 102 (e.g. back wall 107) that are treated during a sweep of the applicator 202, each band 602 having a width corresponding approximately to the length of the applicator tip 210 (see Fig. 2). In each of the figures presented herein,
the bands 602 are shown as horizontal, for the sake of illustration; however, it will be appreciated that in practice the bands will be generally arcuate, corresponding to the rotary nature of the motion during the sweep of the applicator 202 (see hereinafter).

Knowledge of the dimensions of the cavity 102 allows it to be divided up into bands 602 as shown. If the width of the cavity for each band is known, the length of time that the applicator 202 needs to stay at each band 602 can be calculated, such that an equivalent thermal dose (or the required thermal dose) for each band 602 is delivered, as the applicator 202 will only be able to sweep from side to side in a particular band 602 (in between axial movements caused by the linear actuator 504).

Figure 7 shows the treatment device of Fig. 2 during treatment of a specific band of tissue 602. The required thermal dose can be known beforehand through experimental or theoretical thermal analysis techniques. The use of mechanical withdrawal ensures that the results of each treatment will therefore be controlled and can be made consistent.

In relation to safety, the treatment device and system prevents the applicator tip 210 being inserted further than would be safe given the dimensions of the cavity 102. For example, the applicator 202 may be restricted to be able to be inserted no further than the endwall 110 of the cavity 102 (i.e. depth d in Fig. 2), or this distance plus a small amount that was judged to be safe, given that the tissue is slightly elastic.

Angular sensing and angular rate sensing

Figure 8 shows the treatment device of Fig. 2 during treatment of a specific band of tissue. In use, with the position of the applicator 202 fixed relative to the housing 208, the housing 208 is rotated somewhat from side to side (direction of arrows B) typically by the physician so that tip 210 is sweeping over a band 602, and the applicator 202 and tip 210, at any given instant, have an angular displacement with respect to the midline M and an angular velocity.

The angle of the applicator 202 relative to the midline M (or some other reference) is determined by an angular rate sensor (not shown; see hereinafter) mounted within the housing 208. Such an angular rate sensor may be, for example, the CRS03 gyroscope sensor from Silicon Sensing Systems. The angular rate sensor would be zeroed before treatment to record the mid-line M of the patient. It would then
measure the angular rate of movement in the horizontal plane, allowing the angle of the tip 201 to be calculated relative to the patient at any time. (Further gyroscopes (angular sensors) may be used to measure the angular motion also.)

The use of an angular rate sensor enables the system to know the angular rate of applicator 202 sweeping and to calculate the angle of the applicator 202 relative to the zeroing position M at all times. Other gyroscopes may give the angle at all times, allowing the rate of sweeping to be calculated. This allows the system to ensure that the applicator 202 is being moved sufficiently quickly to ensure safety, and to ensure complete coverage of the treatment band 602 the applicator 202 is in. If there is only one angular rate sensor (gyroscope) on the applicator 202, it is orientated such as to record the maximum rate of motion when the applicator 202 is swept from side to side in the manner intended. This automatically makes the system fail safe, as the system could only then under-read the rate of sweeping if the applicator 202 is swept in a way other than intended, making the system more likely to cut power to the applicator 202 if insufficient motion was recorded. For example, this may occur if the applicator 202 is tilted on its side, when the angular rate sensor had been positioned within the applicator 202 so as to record the maximum angular rate of motion when the applicator 202 was not tilted on its side. However, the angular rate sensor (gyroscope) may also be a sensor that detects motion in all 3 dimensions. This enables sweeping to be accurately measured even if the applicator 202 is tilted on its side.

Using an angular rate sensor, such as that given as an example, the sensor gives out an output voltage that is in direct proportion to the rate of motion of the applicator 202. This voltage may be offset from zero. For example, the voltage may be +2.5V (or some other value) when no rotation is measured by the sensor, and this voltage will then rise when the sensor is rotated in one direction, and fall when the sensor is rotated in the other direction. Typically, and for the example commercially available sensor given, this offset voltage needs to be measured with the applicator 202 completely stationary before the applicator 202 is used, to ensure that the offset voltage is correctly set (calibrated). This can be achieved by simply leaving the applicator stationary for a short length of time (such as a few seconds) and recording the output voltage. This voltage then becomes the offset voltage.

The difference in output voltage and the offset voltage is proportional to the rate of rotation of the sensor. This voltage difference then needs to be multiplied by a
conversion factor to give the rate of rotation in the units required, such as
degrees/second, radians/sec. Integrating the rate of rotation over time will give the
angle of the sensor as a function of time. If, for example the voltage difference is
integrated, this will need to be multiplied by a conversion factor to give the angle in
the units required, such as degrees or radians. If the voltage difference was
converted before the integration, then no conversion may be needed. In any case,
the voltage difference is directly proportional to the rate of rotation of the sensor in a
particular plane, and the integral of the voltage difference will give a number that is
directly proportional to the angle of the applicator relative to where this figure was last
reset to zero.

In the case where a gyroscope is used to measure angle directly, the output needs to
be differentiated to give the rate of rotation of the sensor, if this is required for the
application, such as to ensure that the rate of rotation of the applicator exceeded a
certain value.

In relation to safety, the use of an angular rate sensor (or other method of measuring
applicator angle) allows the sweeping of the applicator 202 to be monitored. This
ensures that the applicator 202 does not remain stationary and that the rate of motion
is greater than the rate of motion required to cover the whole of the band in the time
available in that band. As shown in Fig. 8, if the width of the cavity at 40 mm from the
internal os 104 is, for example, 30 mm, and the time available to treat that section of
tissue is 35 seconds, then the whole of the 30 mm wide strip needs to be treated in
35 seconds. Therefore, the rate of motion of the applicator must be sufficient to cover
30 mm in 35 seconds. If it is swept faster than this, then every section of tissue in the
band will have been heated at least once by the microwave field. In order to ensure a
more even coverage, a higher minimum angular rate of motion may be applied. For
example, the minimum rate of motion could be set such that every piece of tissue
within the band 602 had to be heated by the microwave field at least twice. The
minimum rate of motion would then be set such that the applicator 202 would cover a
minimum of 60 mm (all the way to one sidewall and back) in 35 seconds.

To relate the required rate of movement of the applicator tip 210 to the rate of motion
measured by the angular rate sensor, the point at which the applicator 202 is pivoting
around needs to be known. In the case of the uterine cavity, this is likely to be the
internal os 104, but clinical investigation may be used to determine this more
accurately.
For the example shown in Fig. 8, the minimum rate of angular motion required if one
sweep was sufficient to achieve treatment would be given by

\[
\frac{\text{Distance to be covered by applicator tip}}{\text{Distance from internal os to applicator tip \times Seconds available to treat area}} = \text{Radians/sec}
\]

where the distance to be covered was approximately the width of the cavity (30 mm),
the distance from the pivot point to the tip was 40 mm, and 35 seconds was the time
to be spent treating this area.

The use of an angular rate sensor (or pure angle sensor) in conjunction with
applicator force sensors adds additional safety, as described below in relation to Figs
9 to 11.

Force sensing at sidewalls

Figure 9 shows the treatment device of Fig. 2 during treatment, at the end of a band
and contacting the sidewall of the uterus.

When the applicator tip 210 touches the sidewall 108, force is exerted on the
applicator 202 shaft. This is preferably detected and therefore can be used to provide
feedback to the user. For example, the system may provide an audible and/or visual
indication that the sidewall 108 of the uterus (or cavity 102) has been reached, as
shown in Fig. 9.

In one embodiment, force detection is achieved through the use of force sensors on
the applicator 202 shaft, which in the preferred embodiment measure strain (i.e. one
or more strain gauges 214 mounted on the exterior of the applicator 202). The force
on the applicator 202 would cause a bending moment on the applicator 202 shaft.
Strain gauges on the wall of the shaft detect the bending of the shaft and feed this
back to the system controller (not shown). When a threshold strain is reached, the
system warns the user, through audible and/or visual indication, that the applicator
202 is encountering significant resistance.

In an alternative embodiment, the bending moment is used to close a circuit either
directly, or through closing a switch.
Figure 10 is a partial view of a treatment device according to a fourth embodiment of the invention, (a) in unstressed state, and (b) subject to maximum lateral bending. Here, a tube 1002 partially encloses the shaft or rod 406 on the end of which the applicator 202 is mounted. One or more spacers 1004 limit lateral movement. The applicator 202 and rod 406 may be moved into and out of the tube 1002 in the direction of arrows A₁, the tube 1002 being attached to the end of, or mounted integrally within, the housing 208 (not shown). One or more switching elements 1006 are provided at the distal end of the tube 1002. When in the position indicated in Fig. 10(a), the switch (circuit) is open.

However, after pressing on the sidewall 108 (Fig. 9), the rod 406 and or applicator 202 bends causing the switch (circuit) to be closed. The switching elements 1006 may comprise switches that are actuated by mechanical contact from the applicator 202 or rod 406, such as a contact switch. Alternatively, a conductive material may be present on the outer surface of the applicator 202 or rod 406, so that a circuit is closed with one or two contacts on the switching elements upon contact from the applicator 202 or rod 406. Those skilled in the art will recognize that other arrangements may be used.

In relation to safety, the embodiment just described provides the user with information on the resistance encountered by the applicator 202 inside the uterus. This therefore gives the possibility of detecting perforations into the uterine wall by the applicator 202.

Figure 11 shows the treatment device of Fig. 2 during treatment, embedded in the end wall 110 of the uterus 100. If the applicator 202 is stuck in the end wall 110 of the cavity 102 (rather than being free to move inside the cavity) then significantly larger forces will be encountered by the tip 210 over a smaller range of applicator 202 sweeping angles than would be encountered if the tip 210 was not stuck in the end wall 110. This is interpreted by the user, or the system is programmed to cut (or even not apply power) if significant resistance being encountered on either side of a sweep was under a predefined threshold value that may be determined by measurement. The angle would be measured by the angular rate sensor described earlier.
System Integration

As mentioned earlier, any combination of the above-described techniques may be used in embodiments of the invention.

Figure 12 is a partial view of a fully assembled treatment device according to a fifth embodiment of the invention, showing parts enclosed in a reusable handle 1204. Figure 13 is a view of a treatment device of Fig. 12, showing the cervical collar 206. The housing 208 includes a disposable part 1202 and a reusable handle 1204. The linear actuator 504 and gyroscopic chip (angular sensor) 1206 are mounted with the handle 1204.

Figure 14 shows a map 1402 of the uterine cavity generated in a graphical display 1404 by the treatment system according to an embodiment of the present invention. Figure 15 is an updated version of the map 1402 of Fig. 14, showing (shaded) the areas of the uterus wall that have been treated.

Methodology

Using the aforementioned components allows the following preferred methodology to be used. A simulated treatment is carried out without power being applied to the tissue. The applicator 202 is withdrawn by the linear actuator 504 whilst the applicator 202 is moved from side to side. Knowing the location of the applicator tip 210 together with lateral force data on the tip 210 allows the uterine cavity 102 to be mapped out, as at the edges (sidewalls 108) of the cavity additional force is encountered and the location of the applicator tip 210 is known in terms of angle and distance from the internal os 104. Following or during data acquisition during this process, software in the system controller displays a map 1402 in a screen 1404 as illustrated in Fig. 14, in a suitable UI display device (not shown). This may be done more quickly than an actual treatment procedure.

In the event that the map 1402 does not appear as expected, the user may abandon the treatment. In addition, the system may prevent power being applied if the angle between each edge being detected was below a certain limit, as this would indicate that the applicator 202 could be stuck in the end wall 110 rather than within the cavity 108.

If this map 1402 is satisfactory, and shows no sign of a possible perforation by the applicator 202, the applicator tip 210 is then driven out again, and microwave power
applied, whilst the clinician manually sweeps the applicator 202 laterally within the cavity 102. The location and depth of heating (treatment intensity) is then be shown preferably in real-time on the system screen 1404 as shown in Fig. 15, with the applicator 202 being continuously withdrawn by the system as the treatment progresses. The length of time that the user had spent at each position within the cavity 102 could be shown on the map 1402 in the screen 1404 through a different colour in the already treated areas 1502, or a density of a particular colour. A distinctive colour may be used for the current position 1504.

This aforementioned techniques also allow active power management to be implemented. Detection of faster rates of movement of the device by the clinician cause more power to be applied by the system, while slower rates result in less power being applied. In addition, if a particular point had not been sufficiently treated during the first sweep, more power may be applied by the system at that same point as the applicator was swept back, to maximise both efficacy and safety.

If the system does not incorporate force sensors, then the cavity may not be mapped out pre-treatment. Instead, a triangular shape representing the cavity may be displayed on a treatment screen, and the user then sees the position of the tip within this (graphically represented) cavity, and the treatment applied is once again be shown on the screen. However, the pre-treatment mapping may not be carried out to ensure that the applicator had not perforated the wall.

Figure 16 is a schematic illustration of the overall treatment system in accordance with embodiments of the invention. Generally, the treatment system comprises a treatment device 200 and a control system 1600. The treatment device 200 is as described for any of the previously mentioned embodiments. As well as a housing 208 and collar section 206, the treatment device 200 may, depending on the embodiment, incorporate one or more of a strain gauge or switch 1006, an angular rate sensor 1602, a position feedback sensor 1604 and a stepper motor (linear actuator) 504.

The control system 1600 essential comprises a computer 1610 (for example a IBM compatible PC, although other suitable processor based systems may be used) incorporating, or being linked to the treatment device 200 via, various interfacing circuitry. More particularly, the interfacing circuitry may include, depending on the embodiment, a first ADC 1612 for converting the analog strain gauge or switch output
to a digital signal for the computer 1610, a second ADC 1614, for converting the analog angular rate sensor output to a digital signal for the computer 1610, a third ADC 1616, for converting the analog position feedback sensor output to a digital signal for the computer 1610, and a stepper motor control unit 1618, for controlling the stepper motor 504 in response to control signal from the computer 1610.

The control system 1600 also includes a heating energy source, in this case a microwave generator 1620 supplying, in use, via coaxial cable 1622, microwave energy to the treatment device 200 for emission by the applicator 202.

The computer 1610 includes, as part of its user interface (Ul), a display 1624, in which the treatment map (discussed hereinabove), as well as other information, may be displayed to the user. At least part of the software implemented functionality (discussed in more detail later) of the treatment system is schematically illustrated. This functionality includes a first safety trip 1626, whereby microwave power is cut (and a visual and/or audible alarm is output) if the applicator fails to move as directed by the user (e.g. because it is stuck in the endometrial wall). The functionality also includes a second safety trip 1628, whereby microwave power is cut, or prevented from being commenced/applied (and a visual and/or audible alarm is output), if it is determined that excessive force is being applied to the applicator 202, or large forces are being encountered within a very small angle.

The software implemented functionality, according to some embodiments, further includes the applicator withdrawal control algorithm 1630. This is set out in more detail below. Briefly, this algorithm assures that, among other things, once (microwave) power is applied, the applicator is withdrawn (axially) in steps, such that the time between each step (movement) is determined by the time required (within a treatment band - see Fig. 6) to ensure the desired treatment of the tissue (within the ban).
In one embodiment, the applicator withdrawal control algorithm 1630 is as set out in the following (pseudocode).

While system is on do
  Sense treatment operation status
  Do
    Load (blank) treatment map
    For each band in treatment map do
      For each tip position in band do
        Sense bending force sensor status
        While bending force is max do
          cut microwave power
          issue warning indication (display message; sound tone)
        Determine thermal energy applied at current location
        While thermal energy applied > safe threshold do
          cut microwave power
        Sense applied microwave power
        Sense housing-tip distance
        Sense applicator angle
        Determine tip position from distance and angle and store
        From current tip position and stored tip position in current band,
        determine whether band treatment completed
        determine average minimum angular rate over prior period
        While average minimum angular rate is below safe threshold do
          cut microwave power
          issue warning indication (display message; sound tone)
        Paint current treatment map, to include current tip position with colour
corresponding to sensed thermal energy applied
while band treatment not completed
while all bands not treated
while treatment operation in progress

Determine thermal energy applied (1st variant)
From effective time at tip location and sensed applied microwave power for tip location, calculate effective thermal energy applied

Determine thermal energy applied (2nd variant)
Sense temp @ thermocouple
Infer thermal energy applied from sensed temp

Determine tip position from distance and angle and store
Figure 17 shows flow charts schematically illustrating the derivation, according to certain embodiments of the invention, of angular position, axial extension (distance), and x,y positions of the tip 210. In the left hand column is illustrated the procedure for determining angle A relative to an initial direction (for example a starting orientation, or a calibration axis such as the midline M of the patient). In the right hand column is illustrated the procedure for determining the extension E (i.e. The axial distance or displacement of the applicator 202, or of the radiating tip 210, relative to the housing 208, or a predetermined position thereon).

Determine whether band treatment completed
From blank treatment map, determine, for this band, the max applicator angle at RH sidewall and max applicator angle at LH sidewall
determine, for this band, whether stored max sensed +ve angle >= max applicator angle at RH sidewall AND stored max sensed -ve angle >= max applicator angle at LH sidewall AND
Effective thermal energy applied at all positions in band is within desired range

Procedure for mapping endometrial cavity to derive (blank) treatment map

While in pre-treatment phase (power off)
  Extend applicator to depth given by fundal sound/ultrasound measurement
  Instruct user to hold applicator along mid-line of patient
  Set angle at this position as reference angle

For band without two recorded tip locations and applicator extension > 0 do
  While no recorded tip locations
    Instruct user to sweep left
    When bending force sensor = max record tip location and display
  While 1 recorded tip location
    Instruct user to sweep right
    When bending force sensor = max record tip location and display
    If angle between two recorded locations < safe threshold indicate possible perforation to user
    Withdraw 1 step to new band
  When applicator extension = 0 end

As will be appreciated by persons skilled in the art, alternative procedures and algorithms, and variants and extensions, compared with those given above, may be used to implement the techniques according to the invention.
Claims:

1. A treatment device for treating endometrial tissue, comprising:
   - an elongate housing defining an axis, the housing incorporating or having attached thereto a projection for abutting, in use, a body portion associated with the endometrial tissue;
   - an elongate member extending axially from the housing and incorporating a radiation emitting element;
   - an electronically controllable actuator, coupled to the housing and to the elongate member;
   wherein the actuator is adapted to move the elongate member axially relative to the housing by a predetermined step distance along said axis in response to a step control signal.

2. The treatment device of claim 1, wherein the projection comprises a collar shaped for abutting, in use, the cervix or the internal os.

3. The treatment device of claim 1 or 2, wherein said predetermined step distance is approximately equal to the axial length of said radiation emitting element.

4. The treatment device of claim 1 or 2, wherein the actuator is fixedly mounted on the interior of the housing and is adapted to move the elongate member into and out of the housing, or wherein the actuator is fixedly mounted on the elongate member and is adapted to move the elongate member into and out of the housing.

5. The treatment device of any of the preceding claims, wherein the actuator comprises a stepping linear actuator.

6. The treatment device of any of the preceding claims, further including a sensor, fixed to the housing and/or to the elongate member, for providing a signal indicative of the position of the elongate member or of the radiation emitting element relative to the housing or relative to a calibration point.

7. The treatment device of claim 6, further including circuitry for providing a signal indicative of the distance from the housing or from a calibration point to the radiation emitting element or to a part of the elongate member.
8. The treatment device of any of the preceding claims, further including circuitry for providing a signal indicative of the angle relative to a calibration axis of the axis of the elongate member.

9. A treatment system for treating endometrial tissue, comprising:
   the treatment device of any of claims 1 to 8; and
   a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and
   a controller, coupled to the radiation source and to the treatment device, for transmitting the step control signals and/or controlling the supply of energy to the radiation emitting element.

10. The treatment system of claim 9, wherein:
    the controller includes at least a processor and memory, the processor being operable in conjunction with memory for
    (a) receiving said position signals, distance signals and/or angle signals indicative of the position, distance from a calibration point or angle, respectively, of the radiation emitting element;
    (b) in dependence upon the received position signals, distance signal and/or angle signals, transmitting a step control signal to the treatment device, whereby the elongate member is moved axially by said predetermined step distance, for example corresponding to the axial length of said radiation emitting element.

11. The treatment system of claim 10, wherein the system is operable to treat the tissue in successive substantially arcuate bands extending between the sidewalls of the endometrium; and
    wherein the processor is operable in conjunction with memory for generating said step control signal when it is determined from said position signals, distance signals and/or angle signals that the radiation emitting element has passed over and thereby treated the entire area of tissue within a band.

12. A method of treating endometrial tissue, comprising:
    providing a treatment device according to any of claims 1 to 8;
sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue within a substantially arcuate band extending between the sidewalls of the endometrium; and during said sweeping, periodically or aperiodically transmitting a step control signal to the treatment device, whereby the elongate member is moved axially by said predetermined step distance by said linear actuator; thereby treating the endometrial tissue in successive bands.

13. A treatment device for treating endometrial tissue, comprising:
an elongate housing defining an axis;
an elongate member extending axially from the housing and incorporating a radiation emitting element;
a first angular rate sensor, for detecting the angular rate of sweeping of the elongate element through rotation thereof about an axis transverse to the axis of the housing, and providing an angular rate signal indicative of said angular rate.

14. The treatment device of claim 13, wherein the device comprises, instead of a first angular rate sensor, a first angular sensor, for detecting the angular position of the elongate element in a plane parallel to the axis of the housing and relative to a first calibration axis, and providing an angular position signal indicative of said angular position.

15. The treatment device of claim 13 or 14, further comprising a second angular rate sensor, for detecting the angular position of the elongate element in a second plane perpendicular to the axis of the housing and relative to a second calibration axis, and providing a second angular position signal indicative of said angular position in said second plane.

16. A treatment system for treating endometrial tissue, comprising:
the treatment device of claim 13;
circuitry, coupled to receive the angular rate signal and generate a first control signal if said angular rate signal meets predetermined criteria and/or generating a second control signal if said angular rate signal does not meet said predetermined criteria.
17. The treatment system of claim 16, wherein
   said circuitry is adapted to determine the minimum angular rate over a period;
   and
   said predetermined criteria include the determined minimum angular rate being above a predetermined threshold.

18. The treatment system of claim 17, further including:
   circuitry for storing a first calibration value, said first calibration value being the signal output by the first angular rate sensor when the elongate member is stationary, and/or for storing a second calibration value, said second calibration value being the signal output by the second angular rate sensor when the elongate member is stationary.

19. The treatment system of any of claims 13 to 18, further including:
   circuitry for integrating said angular rate signal thereby deriving the angular position of the elongate member relative to a calibration orientation.

20. A treatment system for treating endometrial tissue, comprising:
   the treatment device of claim 14 or 15;
   circuitry, coupled to receive the angular position signal(s) and generate a control signal if said angular position signal(s) meets predetermined criteria.

21. A treatment system, comprising:
   the treatment device of any of claims 13 to 15;
   a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and
   a controller, coupled to the radiation source and to the treatment device, for transmitting control signals and/or controlling the supply of energy to the radiation emitting element.

22. The treatment system of claim 21, further comprising circuitry for providing a signal indicative of the distance from the housing or from a calibration point to the radiation emitting element or to a part of the elongate member; and
   wherein the controller includes a processor, memory and user interface (UI).

23. The treatment system of claim 21, wherein:
   the processor is operable in conjunction with memory for
(c) logging position signals, distance signals and/or angle signals indicative of the position, distance from a calibration point or angle, respectively, of the radiation emitting element;

(d) displaying in the UI a graphical representation of the endometrium, the graphical representation including (i) areas of the endometrium that have not been treated, (ii) areas of the endometrium that have been treated, and/or (iii) the current position within the endometrium of the radiation emitting element.

24. The treatment system of claim 23, wherein:

(d) comprises displaying in different colours and/or with different shades each of said (i) areas of the endometrium that have not been treated, (ii) areas of the endometrium that have been treated, and/or (iii) current position within the endometrium of the radiation emitting element.

25. The treatment system of claim 24, wherein:

the processing is operable in conjunction with memory for

(e) receiving radiation power signals, indicative of the instantaneous power of the radiation emitted by the radiation emitting element; and

(f) in dependence upon said (A) radiation power signals and (B) position signals, distance signals and/or angle signals, displaying, in the areas of the uterus that have been treated, elemental parts thereof in a colour corresponding to the amount of thermal energy applied thereto by the radiation emitting element.

26. A method of treating endometrial tissue, comprising:

providing a treatment device according to any of claims 13 to 15;

sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue in a substantially arcuate band extending between the sidewalls of the endometrium; and
controlling the supply of energy to the radiation emitting element in
dependence upon at least the sensed angular rate or angular position of the elongate
member.

27. A method of treating endometrial tissue, comprising:
providing a treatment system according to claim 22;
sweeping the treatment device from side to side over the endometrial tissue
by rotating about an axis transverse to the axis of the housing, whereby the radiation
emitting element system is operable to treat the tissue in a substantially arcuate band
extending between the sidewalls of the endometrium; and
operating the processor in conjunction with memory to
log position signals, distance signals and/or angle signals indicative of the
position, distance from a calibration point or angle, respectively, of the radiation
emitting element; and
display in the UI a graphical representation of the endometrium, the graphical
representation including (i) areas of the endometrium that have been treated, (ii)
areas of the endometrium that have been treated, and/or (iii) the current position
within the endometrium of the radiation emitting element.

28. A treatment device for treating endometrial tissue, comprising:
an elongate housing defining an axis;
an elongate member extending axially from the housing and incorporating a
radiation emitting element;
wherein at least part of the elongate member is made of a resilient material
whereby, in use, the elongate member may bend away from said axis; and
wherein the device further includes a transverse displacement sensor for
providing a displacement signal indicative of the extent of bending of said elongate
member.

29. The treatment device of claim 28, wherein the transverse displacement
sensor comprises at least one strain gauge mounted in or on the elongate member.

30. The treatment device of claim 29, wherein the transverse displacement
sensor comprises a plurality of strain gauges, the strain gauges being mounted
circumferentially around the exterior of the elongate member.
31. The treatment device of claim 28, further comprising a tube partially enclosing the elongate member;

    wherein the transverse displacement sensor comprises a switch formed at least partially by elements at one end of the tube that may be engaged, in use, by the elongate member.

32. The treatment device of claim 31, wherein the elements comprise first electrical contacts, the elongate member includes second electrical contacts on the side thereof,

    wherein, in use, abutment of said first and second electrical contacts when the bending of the elongate member has reached a predetermined extent closes a switch, thereby generating said displacement signal.

33. A treatment system for treating endometrial tissue, comprising:

    the treatment device of any of claims 28 to 32; and

    a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and

    a controller, coupled to the radiation source and to the treatment device, for transmitting control signals and/or controlling the supply of energy to the radiation emitting element.

34. The treatment system of claim 33, wherein the controller includes at least a processor and memory, and wherein the processor is operable to in conjunction with memory to

    (i) receive said displacement signal from the transverse displacement sensor; and

    (ii) adjust the supply of energy to the radiation emitting element when said displacement signal indicates the extent of bending of said elongate member is above a predetermined bending threshold.

35. The treatment system of claim 34, wherein (ii) comprises cutting the supply of energy to the radiation emitting element when said displacement signal indicates the extent of bending of said elongate member is above a predetermined bending threshold.
36. A method of treating endometrial tissue, comprising:
   providing a treatment system, the treatment system comprising the treatment device of any of claims 28 to 32, a radiation source, for example a microwave radiation source, coupled to the treatment device, for supplying energy to the radiation emitting element; and a controller, coupled to the radiation source and to the treatment device, for transmitting control signals and/or controlling the supply of energy to the radiation emitting element.
   sweeping the treatment device from side to side over the endometrial tissue by rotating about an axis transverse to the axis of the housing, whereby the radiation emitting element system is operable to treat the tissue in a substantially arcuate band extending between the sidewalls of the endometrium; and
   operating the controller to
   (iii) receive said displacement signal from the transverse displacement sensor; and
   (iv) adjust the supply of energy to the radiation emitting element when said displacement signal indicates the extent of bending of said elongate member is above a predetermined bending threshold.

37. A treatment device substantially as hereinbefore described with reference to Figs 2 to 17 of the accompanying drawings.

38. A treatment system substantially as hereinbefore described with reference to Figs 2 to 17 of the accompanying drawings.

39. A method of treating endometrial tissue, substantially as hereinbefore described with reference to Figs 2 to 17 of the accompanying drawings.
Fig. 14

MICROWAVE: OFF

Treatment Time (mm:ss): 00:00

Scanning uterine cavity

Fig. 15

MICROWAVE: ON

Treatment Time (mm:ss): 01:14

Treatment in progress.....
Calculation to obtain angle relative to initial direction

- Input signal (voltage)
- Subtract bias value (value set such that output is zero when the rate sensor is still)
- Integrate signal with respect to time
- Multiply result by calibration factor to give output in required units (e.g., degrees)
- Output - Angle

Calculation to obtain extension

- Input signal (voltage) from potentiometer
- Signal (x) directly proportional to extension in required units (y) therefore y = mx + c where m and c are constants
- Output - Extension in required units

Angle - A
Extension - E

To plot on cartesian grid
x = E sinA
y = E cosA

Fig. 17
### A. CLASSIFICATION OF SUBJECT MATTER

**INV.** A61B18/18  
**ADD.** A61N5/10

According to International Patent Classification (IPC) or to both national classification and IPC

### B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61B  A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database consulted during the international search (name of data base and where practical, search terms used)

EPO-Internal

### C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
<th>Citation of document with indication, where appropriate of the relevant passages</th>
<th>Relevant to claim No</th>
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<tr>
<td>X</td>
<td>EP 0 717 965 A (LASER IND LTD [IL]) 26 June 1996 (1996-06-26) column 2, line 40 - column 4, line 15; figures</td>
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### X

Further documents are listed in the continuation of Box C  

### X

See patent family annex

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Form PCT/ISA/210 (second sheet) (April 2005)
### DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
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<th>Category</th>
<th>Citation of document with indication where appropriate of the relevant passages</th>
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**INTERNATIONAL SEARCH REPORT**

### Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **[Y]** Claims Nos. 12, 26, 27, 36, 37, 38, 39
   - because they relate to subject matter not required to be searched by this Authority, namely:
     - Rule 39 1(iv) PCT - Method for treatment of the human or animal body by surgery
     - Rule 39 1(iv) PCT - Method for treatment of the human or animal body by therapy

2. **[X]** Claims Nos. 37, 38, 39
   - because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
     - see **FURTHER INFORMATION** sheet PCT/ISA/210

3. **☐** Claims Nos. 
   - because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6 4(a)

### Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application as follows:

- see additional sheet

1. **[Y]** As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid specifically claims Nos.

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims, it is covered by claims Nos.

**Remark on Protest**

- **☐** The additional search fees were accompanied by the applicant's protest and where applicable the payment of a protest fee.
- **☐** The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- **[X]** No protest accompanied the payment of additional search fees.
Continuation of Box II.1

Claims Nos.: 12, 26, 27, 36, 37, 38, 39

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

Continuation of Box II.2

Claims Nos.: 37, 38, 39

The subject-matter of claims 37-39 tries to be defined by referring to the drawings, which cannot provide a clear definition of the scope of the claims in the sense of Article 6 PCT, see also PCT Guidelines 5.31-5.33.
This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-11
   Endometrial tissue treatment device with an elongate member extending axially from an elongate housing and incorporating a radiation emitting device, comprising a controlable actuator to move the elongate member axially relative to the housing.

2. Claims: 13-25
   Endometrial tissue treatment device with an elongate member extending axially from an elongate housing and incorporating a radiation emitting device, comprising an angular rate sensor for detecting the angular rate of sweeping of the elongate element.

3. Claims: 28-35
   Endometrial tissue treatment device with an elongate member extending axially from an elongate housing and incorporating a radiation emitting device, comprising a transverse displacement sensor to measure the extent of bending of said elongate member.
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